

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 169

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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JAMES P. MORRISON and SAMUEL K. YUE,

Junior Party,<sup>1</sup>

v.

PAUL D. MANNHEIMER and DAVID E. GOODMAN,

Junior Party,<sup>2</sup>

v.

JOHANNES P. BUSCHMANN,

Senior Party.<sup>3</sup>

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Patent Interference No. 103,197

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<sup>1</sup> Application Serial No. 07/530,875, filed May 29, 1990. Assigned to PHox Medical Optics, Inc.

<sup>2</sup> Application Serial No. 07/752,168, filed August 22, 1991. Assigned to Nellcor, Inc. Accorded benefit of Serial No. 07/373,342, filed June 29, 1989.

<sup>3</sup> Application Serial No. 07/573,225, filed September 21, 1990. Unassigned. Accorded benefit of PCT/EP/00170, filed February 24, 1989, and Fed. Rep. Germany Application P38 10008.8-35, filed March 24, 1988.

JUDGMENT UNDER 37 CFR § 1.658

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URYNOWICZ, MARTIN, and LEE, Administrative Patent Judges.

MARTIN, Administrative Patent Judge.

The subject matter in this interference relates to measuring the oxygen saturation level in tissue, such as fetal scalp tissue, by invasively inserting a radiation emitter or a radiation sensor or both into the tissue and measuring radiation transmission through the tissue. Three species of devices are disclosed by the parties: (1) a species having both the emitter and the sensor issue inside the tissue being examined, i.e., an emitter-in/sensor-in species, hereinafter referred to as the I-I species; (2) an emitter-in/sensor-out species (I-O species); and (3) an emitter-out/sensor-in species (O-I species).

#### **A. Background**

Prior to declaration of the interference, the examiner suggested identical claims for copying by each applicant for purposes of an interference.<sup>4</sup> The suggested claims were

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<sup>4</sup> The copied claims are Morrison's claim 27, Mannheimer's claim 38, and Buschmann's claim 106.

copied by each applicant and the interference was declared with a single count, Count 1, which was identical to the copied claims, which was limited to the I-O species.<sup>5</sup>

Only Mannheimer and Buschmann filed preliminary motions, of which we will address only those motions whose decisions we have been asked to review or which altered the designation of claims corresponding to the count. Mannheimer's unopposed § 1.633(c)(3) motion<sup>6</sup> to designate Buschmann's claim 18 as

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<sup>5</sup> Count 1 read as follows

A perinatal sensing system for determining blood oxygenation within a body comprising:

means for generating light at an interstitial subcutaneous location within the body;

means for transmitting the generated light from the subcutaneous location to an epidermal location of the body, wherein the transmitted light passing through the body changes in intensity in response to different levels of blood oxygenation; and

means for detecting the changes in the intensity of the light transmitted through to the epidermal location in order to determine the blood oxygenation within the body.

The following claims were designated as corresponding to Count 1:

Morrison claims 1-5, 8-24, 27, and 28.

Mannheimer claims 1-11, 18-21, 86-104, and 106.

Buschmann claims 1-9, 12-14, 19, and 26-38.

<sup>6</sup> Mannheimer Motion 15 (paper No. 31).

corresponding to the count was granted.<sup>7</sup> Mannheimer's § 1.633(a) motion<sup>8</sup> alleging unpatentability of Buschmann's claims 1-9, 12-14, 19, and 27-37<sup>9</sup> based on N.S. Kapany, Fiber Optics, Principles and Applications 184-205 (Academic Press 1967) (hereinafter, Kapany), was granted as to Buschmann's claims 1-3, 5-7, 12, 14, 19, 29, and 32 and denied as to Buschmann's claims 4, 8, 9, 13, 18, 27, 28, 30, 31, and 33-37.<sup>10</sup> As Buschmann has not asked for review of the granting of the motion with respect to those claims, judgment is being entered infra against them on the ground of unpatentability over Kapany without further discussion.

Mannheimer and Buschmann, correctly noting that because Count 1 is limited to the I-O species it improperly excludes the involved claims which encompass or recite the other two

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<sup>7</sup> Decisions on Motions (paper No. 75) (hereinafter "Dec. on Motions"), at 4.

<sup>8</sup> Mannheimer Motion 1 (paper No. 16).

<sup>9</sup> The motion did not attack Buschmann claims 26 and 38.

<sup>10</sup> Dec. on Motions at 4-16.

species,<sup>11</sup> each moved under § 1.633(c)(1) to replace Count 1 with one or more other proposed counts. Specifically, Buschmann<sup>12</sup> proposed to either (i) add O-I and I-I species Counts 2 and 3 and replace Count 1 with a different I-O species Count 4, or (ii) replace Count 1 with a generic Count 5. The Administrative Patent Judge (APJ), unpersuaded by the motion that the three species are separately patentable, as is necessary to justify plural counts,<sup>13</sup> denied it with respect to substituting proposed Counts 2-4 but granted it with respect to substituting proposed Count 5.<sup>14</sup> For the same reasons, the APJ denied Mannheimer's motions<sup>15</sup> to replace Count 1 with species Counts MAN-1, MAN-2, and MAN-3.<sup>16</sup> Accordingly, the APJ redeclared the interference with Mannheimer's proposed generic

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<sup>11</sup> As explained in § 1.601(f), "At the time the interference is initially declared, a count should be broad enough to encompass all of the claims that are patentable over the prior art and designated to correspond to the count."

<sup>12</sup> Buschmann Motion II, paper No. 13.

<sup>13</sup> Section 1.601(f) provides that "[w]hen there is more than one count, each count shall define a separate patentable invention."

<sup>14</sup> Dec. on Motions at 17-18.

<sup>15</sup> Mannheimer Motions Nos. 6, 9, and 12.

<sup>16</sup> Dec. on Motions at 19-20.

Count 5, which reads as follows and is currently the sole count in the interference:<sup>17</sup>

A method of monitoring the condition of living tissue with a monitoring device comprising a radiation emitter sensor area and a radiation sensor [sic, sensor sensor] area, said method comprising invasively sticking at least one sensor area into said tissue, emitting radiation from said radiation emitt[er] sensor area to transilluminate tissue between the sensor areas, and monitoring the transillumination by means of said radiation sensor [sensor] area.

Mannheimer also moved under § 1.633(c)(2)<sup>18</sup> to add new claims 107 and 108 to be designated as corresponding to proposed counts MAN-1 and MAN-2, respectively, neither of which the APJ agreed to adopt. Nevertheless, the APJ granted the § 1.633(c)(2) motions, presumably on the ground the proposed claims are directed to species within generic Count 5. The APJ also granted Buschmann's proposed amendment of claim 1 and addition of new claims 39 and 40, which he treated as a § 1.633(i)/1.633(c) motion.<sup>19</sup> The redeclaration notice designated the following claims as corresponding to Count 5:

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<sup>17</sup> Id. at 17-18.

<sup>18</sup> Mannheimer Motions 7 and 10 (paper Nos. 23 and 26).

<sup>19</sup> Dec. on Motions at 19-22.



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Morrison claims 1-5, 8-24, 27, and 28.

Mannheimer claims 1-11, 18-21, 86-104, 106 and 107.

Buschmann claims 1-9, 12-14, 18, 19, and 26-40.

The failure of the notice to include Mannheimer's claim 108 has been corrected by a second redeclaration notice mailed herewith.<sup>20</sup>

Buschmann filed a request for reconsideration<sup>21</sup> of some of the decisions on motions, which the APJ dismissed-in-part and denied-in-part.<sup>22</sup>

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<sup>20</sup> Paper No. 167.

<sup>21</sup> Paper No. 83.

<sup>22</sup> Paper No. 92, at 9-10.

**B. The issues**

The issues before us are:

(1) whether Mannheimer's § 1.633(a) motion should be granted to the extent it asserts the unpatentability of Buschmann claim 28 and other Buschmann claims over Kapany;<sup>23</sup>

(2) whether, as Mannheimer contends, all claims directed to the I-I species are unpatentable over Kapany and that generic Count 5 therefore should be replaced by Buschmann's proposed Counts 2 and 4, which are limited to the O-I and I-O species, respectively, or by Mannheimer's proposed Count MAN-3, which is limited to both of these species;

(3) whether, as requested in his § 1.635 motion, Morrison should be granted leave to file the corrected preliminary statement that accompanied the motion;

(4) whether, as urged in Buschmann's motion<sup>24</sup> under §§ 1.635 and 1.656(h), some of Morrison's priority evidence should be suppressed; and

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<sup>23</sup> As Morrison's opening brief does not rely or discuss any of the other references cited in the motion, they have not been considered. See Photis v. Lunkenheimer, 225 USPQ 948, 950 (Bd.Pat.Int. 1984) (matters not raised in the brief are ordinarily regarded as abandoned).

<sup>24</sup> Paper No. 154.

(5) whether Morrison and Yue<sup>25</sup> have demonstrated they are entitled to an award of judgement on the issue of priority.

**C. The alleged unpatentability of Buschmann's claims over Kapany**

The APJ granted Mannheimer's § 1.633(a) motion with respect to many of Buschmann's invasive non-oximetry claims, i.e., claims that require invasively sticking a radiation emitter or a radiation sensor into tissue but are not limited to oximetry of any type (i.e., pulse or non-pulse). These are claims 1-3, 5-7, 12, 14, 19, 29, and 32, which Buschmann has effectively conceded are unpatentable over the prior art by not seeking review of this holding by the APJ.<sup>26</sup> However, the APJ denied the motion as to some of Buschmann's other invasive non-oximetry claims (i.e., claims 8, 9, 13, 18, 30, and 35-37) on the ground that they recite elements not suggested by the prior art, such as a spiral needle (claim 8). The APJ also

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<sup>25</sup> The party Morrison is hereinafter referred to as either Morrison or Morrison and Yue. Inventors James Morrison and Samuel Yue are referred to as Dr. Morrison and Dr. Yue.

<sup>26</sup> As Morrison correctly notes, claim 29 is virtually identical to count 5, the scope of which is discussed below.

denied the motion with respect to all of Buschmann's invasive oximetry claims, which the APJ held explicitly or implicitly recite invasive pulse or non-pulse oximetry by measuring radiation transmitted through tissue (i.e., claims 4, 27, 28, 33, 34).<sup>27</sup>

Although Mannheimer's opening brief (at 21) requests that "[t]he question of obviousness of claims, such as Buschmann's claim 28, . . . be addressed by the Board in view of the arguments and evidence presented herein," the only claim that is specifically discussed in the brief is claim 28. Consequently, we will limit our consideration of patentability to that claim, which is directed to the I-I species and reads as follows:

28. A perinatal sensing system for determining blood oxygen saturation within a body tissue by transillumination wherein the light transmission changes in intensity in response to different levels of oxygen saturation comprising:

means for generating light at a first interstitial subcutaneous location within the tissue; and

means at a second interstitial subcutaneous location within the tissue for detecting the changes in the intensity of the light transmitted between the first and second location in order to determine the blood oxygenation within the tissue.

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<sup>27</sup> Dec. on Motions at 15.

Because Buschmann's involved claims are not patent claims, Mannheimer's burden of proof with respect to proving unpatentability is a preponderance of the evidence. See Bruning v. Hirose, 161 F.3d 681, , 48 USPQ2d 1934, 1938(Fed. Cir.

1998)("[T]his court holds that, during an interference involving a patent issued from an application that was copending with the interfering application, the appropriate standard of proof for validity challenges is the preponderance of the evidence standard.").

The first matter to consider is, of course, claim construction. As explained in In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997), "the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." See also In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1321-22 (Fed. Cir. 1989):

During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. See In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969) (before the application is granted, there is no reason to read into the claim the limitations of the specification). The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. Burlington Industries, Inc. v. Quigg, 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed. Cir. 1987); In re Yamamoto, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984). The issued claims are the measure of the protected right. United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 232, 55 USPQ 381, 383-84 (1942) (citing General Electric Corp. v. Wabash Appliance Corp., 304 U.S. 364, 369, 37 USPQ 466, 468-69 (1938)).

We note at the outset that Mannheimer does not take issue with the APJ's decision that the term "tissue" as used in Buschmann's claims excludes blood located in a cardiac chamber or in a blood conduit, such as an artery or vein.<sup>28</sup> Buschmann's principal argument for patentability is that claim 28 is implicitly limited to pulse oximetry, because the function of "detecting the changes in the intensity of the light . . . in order to determine the blood oxygenation within the tissue" (our emphasis) refers to detecting the amplitude

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<sup>28</sup> Dec. on Motions at 4.

of the modulations in the intensity of the transmitted light caused by the pulsations of arterial blood in the tissue.<sup>29</sup> We agree with Mannheimer that this interpretation of the phrase "changes in intensity of the light" ignores the preamble, which explains that "the light transmission changes in intensity in response to different levels of oxygen saturation." This language makes it clear that "detecting the changes in the intensity of the light" refers to detecting changes caused by variations in the oxygen level, not changes caused by arterial pulsations. Since, as Mannheimer correctly observes, changes in light transmission due to variations in oxygen saturation level can be measured using either pulse oximetry or non-pulse oximetry, the claim is not limited to pulse oximetry.

Turning now to Kapany, the APJ denied the motion with respect to claim 28 because he was not persuaded that Kapany discloses or suggests invasive oximetry (pulse or otherwise) by measuring the transmission of radiation through tissue,<sup>30</sup> in

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<sup>29</sup> B.Br. 110.

<sup>30</sup> Dec. on Motions at 13-15.

which position Buschmann concurs.<sup>31</sup> Mannheimer contends that this interpretation is incorrect because it views Kapany's Section 2 ("Hypodermic Probe") and Section 3 ("In Vivo Spectrophotometry") in isolation rather than in combination and that Kapany teaches using the hypodermic probes of Section 2 for in vivo spectrophotometric examination of tissue, including oximetric analysis of tissue.<sup>32</sup> In support of this interpretation, Mannheimer places particular emphasis on the language we have underlined below in the quotations from Kapany. Section 2, which spans pages 185-88 and discusses techniques for obtaining images of tissue areas, begins as follows:

## **2. Hypodermic Probe**

Numerous ingenious approaches have been attempted for the microscopic examination of living human tissue under the skin without an incision. In an ideal instrument for such applications, the optical system should be capable of yielding resolution that approaches the wavelength of light so that the tissues and cells may be observed microscopically. The system should also be capable of illuminating and transmitting images in the ultraviolet, visible, and near-infrared regions of the spectrum. A fiber optics hypodermic probe has been developed which is capable of fulfilling most of these

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<sup>31</sup> B.Br. 119.

<sup>32</sup> Opening Brief at 18-19.



requirements. Basically, the instrument consists of a 5-F-diam[eter] bundle of rigid, fused fibers in a standard 15-19 gage hypodermic needle. [Our emphasis.]

Kapany goes on to explain (p. 186, 2d full para.) that Figure 7.16 shows several techniques for illuminating the tissue under examination, including a transillumination technique (see Fig. 16(b)) that employs two axially aligned hypodermic probes, one for supplying illuminating radiation to the tissue and the other to receive the radiation that is transmitted through the tissue region. Kapany notes that because in most subcutaneous tissues gross changes in color or composition are not observable, such tissues are ordinarily observed under a polarizing microscope, phase contrast microscope, or interference microscope (p. 188, lines 15-18). It is also possible to stain subcutaneous tissue using a very narrow auxiliary channel in the hypodermic probe (p. 188, lines 20-22) or to use the probe in the fluorescence mode by ultraviolet radiation (p. 188, lines 26-30).

Section 2 does not discuss using hypodermic probes for spectrophotometry in general or for oximetry in particular. Instead, those applications are described in Section 3, which spans pages 188-97, and begins as follows:

### 3. In Vivo Spectrophotometry

Whereas reflection and transmission spectrophotometry of specimens in vitro are well established [end note omitted], these techniques are not practical when a specimen is in a remote location and in a dynamic state. Under such conditions, if the specimen is located in a normal channel in the body, a flexible fiber bundle can be used to transmit light from an external source to the specimen and another bundle used to return the signal from the specimen to an appropriate detector. When the specimen is located subcutaneously, then it is possible to use a fiber optics hypodermic probe in which a rigid fiber bundle is used to illuminate the specimen as well as to return the signal to the detector for processing. The mode of illumination would be dependent on whether the reflectance, transmittance, or fluorescence property of the specimen is to be measured. The distal end configuration is governed by the optical conditions to which a tissue is most sensitive. [Our emphasis.]

. . . .

An example of a remote spectrophotometer that has received considerable attention is that used in the field of cardiac and vascular oximetry [end notes omitted]. One of the principal measurements required by cardiologists is the oxy-hemoglobin concentration of the blood in vitro. A method commonly used for this purpose is one in which a flexible hollow catheter is inserted into the cardiac chamber and a sample of blood is removed for chemical analysis by the Van Slyke method or the spectrophotometric method. Obviously, this procedure results in considerable delay and is not amenable to measurements of the spatial or temporal variations of oxyhemoglobin concentration in various regions and in a dynamic state.

Figure 7.18 shows a diagram of the in vivo spectrophotometer system for cardiac oximetry and three different optical configurations for the distal end. In this device, the light is condensed onto a fiber bundle

that conducts it to the distal end. The return signal is passed

through appropriate filters (640- and 805-mF wavelength) and is incident on a photodetector.

The bottom of page 190 includes two equations showing how oxygen saturation can be obtained from the returned signal.

Figure 7.18 (p. 191) shows three different distal ends for a fiber optics oximetry catheter. Of the three optical configurations shown in Figure 7.18 (p. 191), the most relevant to claim 28, because it recites an I-I device, is the "transmission type" configuration shown in Figure 7.18(c), which measures radiation transmitted through the volume of cardiac or vascular blood in the region of the notch near the distal end.<sup>33</sup> Though Kapany does not state how these fiber optics oximetry catheters are introduced into the body to reach the target cardiac chamber or vessel, it is apparent that they are to be inserted through a sheath or hollow catheter that extends into

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<sup>33</sup> We assume that Mannheimer's failure to argue that this device anticipates Buschmann claim 28 is due to his agreement with the Buschmann and the APJ that the term "tissue" as used in that claim excludes oximetric analysis of blood by a device located in a cardiac chamber, artery, or vein.

the target vessel or a vessel which leads to the target cardiac chamber, e.g., a femoral artery or jugular vein.

Kapany also describes using a fiber optics catheter inside a hypodermic needle to measure oxygen in peripheral vessels:<sup>34</sup>

This remote spectrophotometer using fiber optics has also been used for the measurement of dye concentration. Since the return signal on the instrument is a direct function of the flow velocity, it should be possible, with appropriate calibrations, to deduce the flow velocity. With appropriate designs of catheter probes, it is possible to use this technique for long-term monitoring of oxygen saturation within peripheral vessels. Figure 7.26a shows a photograph of a catheter that has a hypodermic needle at the tip.

Kapany's only discussion of measuring the oxygen saturation of blood in tissue (as opposed to an artery, vein, or cardiac chamber) is the following discussion of a non-invasive, clip-on oximeter probe:

Figure 7.26b shows another catheter design for precise ear oximetry. In this case, the fiber bundle is divided in two parts to provide sharp curves to the bundles so that one end may be placed in front of the ear lobe and the other in back of the ear lobe. [Page 197, lines 5-8].

Section 3 concludes with the following paragraph:

The in vivo oximeter has been discussed at some

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<sup>34</sup> Paragraph bridging pages 195 and 197.

length merely to give an example of the experiments that have been made with a fiber optics remote spectrophotometer. Similar applications for use in the genitourinary tract, general endoscopic examination, and studies of various types of affected and unaffected tissues within the body are possible. With the availability of high-quality fibers that can transmit light from 3500 D to 4 F and from 1 to 8 F, it has become possible to study the fluorescence or associated phenomena of remotely located specimens inside the human body. [Our emphasis.] [Page 197, 1st full para.]

Based on the underlined language in this and the other quoted passages, Mannheimer argues<sup>35</sup> that "Kapany clearly teaches using any of the [hypodermic] probes of Fig. 7.16 as well as the probes of Fig. 7.18 for the examination of living tissue in general and, in particular, for oximetry," citing the following testimony of his expert witness, David Swedlow (MANR 76-77, ¶ 6):

6. Clearly the statements referred to above by Kapany of using "a fiber optics hypodermic probe" (Page 189 last line) for in vivo spectrophotomet[ry] (including particularly oximetry) for studying "various types of affected and unaffected tissues within the body" (page 197 lines 12-13) establishes a clear connection between the pages and teaches one of ordinary skill in the art that for oximetry applications, other than the specific cardiac oximetry application experiment that had been discussed, where "tissues within the body" are to be examined any one of the "hypodermic probes" previously described in pages 184-188 for examining "living human

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<sup>35</sup> Opening Brief at 18-19.

tissue[]" (Page 185, Section 2, first sentence; and Page 197, line 13) would be appropriate. Accordingly, in my opinion, Kapany clearly teaches using any of the probes of figure 7.16 as well as the probes of figure 7.18 for examination of living tissue in general and in particular for oximetry.

We agree, up to a point. As noted earlier, the first paragraph of Section 3 ("In Vivo Spectrophotometry") states that "[w]hen the specimen is located subcutaneously, then it is possible to use a fiber optics hypodermic probe in which a rigid fiber bundle is used to illuminate the specimen as well as to return the signal to the detector for [spectrophotometric] processing" (sentence bridging pp. 189-90). We agree that it would have been obvious to employ any of the hypodermic probe configurations of Figure 7.16 for this purpose, even though they are described only in connection obtaining images for microscopic viewing. Thus, it would have been obvious to use the hypodermic probe apparatus of Figure 7.16(b) or 7.16(c) to perform an invasive spectrophotometric analysis of the tissue between the probe tips by comparing the light that is emitted by one probe with the light that is transmitted through the tissue and received by the other. However, while Kapany broadly suggests invasive transilluminative spectrophotometric analysis of tissue, he

does not specifically suggest that this analysis can take the form of an oximetric analysis, as opposed to other types of spectrophotometric analysis, such as "fluorescence or associated phenomena of remotely located specimens in the human body" (p. 197, lines 14-15). The only specific reference in Kapany to measuring oxygen saturation of the blood in tissue is the brief discussion (p. 197, lines 5-8) of the non-invasive ear lobe oximeter attachment shown in Figure 26(b). Kapany does not suggest why it would be desirable to use an invasive technique to obtain the oxygen saturation level of blood in a patient's tissue when the same information can be obtained non-invasively, using the ear lobe attachment shown in Figure 7.26(b) (p. 198). That is, Kapany does not suggest the desirability of measuring the oxygen saturation level of blood in a tissue specimen that cannot be reached using a non-invasive technique. Nor does Kapany otherwise imply that the term "affected . . . tissues" (p. 197, lines 12-13) may refer to tissues including blood having low oxygen saturation. For the foregoing reasons, we believe one skilled in the art would not have construed Kapany's statements that "[t]he in vivo oximeter has been discussed at

some length merely to give an example of the experiments that have been made with a fiber optics remote spectrophotometer" and "[s]imilar applications for use in the genitourinary tract, general endoscopic examination, and studies of various types of affected and unaffected tissues within the body are possible" (p. 197, lines 9-13) as specifically suggesting invasive oximetric analysis of tissue.

For the foregoing reasons, Mannheimer has failed to demonstrate by a preponderance of the evidence that the subject matter of claim 28 or any other Buschmann claim as to which the

§ 1.633(a) motion was denied is anticipated by or obvious in view of Kapany.



**D. Morrison's § 1.635 motion for leave to  
file a corrected preliminary statement**

Morrison's motion<sup>36</sup> under § 1.635 and 1.628(a)<sup>37</sup> for leave to file a corrected preliminary statement<sup>38</sup> explains (at 2) that the original preliminary statement<sup>39</sup> contains a material error in that it gave March 15, 1988, as the date of the first drawing when in fact the date of the first drawing, which was discovered after the original preliminary statement was filed and is now identified as Morrison Exhibit (MX) 42, which consists of five pages of drawings and handwritten notes allegedly made on November 24, 1987. Although not stated in

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<sup>36</sup> Paper No. 114, filed September 18, 1995.

<sup>37</sup> Section 1.628(a) reads as follows:

(a) A material error arising through inadvertence or mistake in connection with a preliminary statement or drawings or a written description submitted therewith or omitted therefrom, may be corrected by a motion (§ 1.635) for leave to file a corrected statement. The motion shall be supported by an affidavit stating the date the error was first discovered, shall be accompanied by the corrected statement and shall be filed as soon as practical after discovery of the error. If filed on or after the date set by the administrative patent judge for service of preliminary statements, the motion shall also show that correction of the error is essential to the interest of justice.

<sup>38</sup> Also paper No. 114.

<sup>39</sup> Paper No. 35.

the motion, the corrected preliminary statement, citing this exhibit, also gives November 24, 1987, rather than March 15, 1988, as the date of the first written description of the invention. Neither Buschmann nor Mannheimer filed an opposition to the motion. However, Buschmann now argues in his motion to suppress<sup>40</sup> (at 1) that "Morrison has not given any reason in law or equity which would support the entry over two years after declaration of the interference of a Corrected Preliminary Statement with a new first drawing, date of first drawing, first written description, and date of first written description." As Morrison correctly notes in his opposition<sup>41</sup> to the motion to suppress, his motion for leave to file the corrected preliminary statement is actually moot, because he has no need to rely on the earlier date alleged therein, for the March 15, 1988, date given in his original preliminary statement for the first drawing and the first written description precedes Buschmann's March 24, 1988, German

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<sup>40</sup> Paper No. 154, filed October 3, 1996.

<sup>41</sup> Paper No. 159.

benefit date.<sup>42</sup> While the original preliminary statement precludes Morrison from proving dates prior to March 15, 1988, it does not preclude him from relying on earlier acts to prove that date. Botnen v. Durnen, 179 F.2d 249, 252, 84 USPQ 270, 273 (CCPA 1949). Morrison's § 1.635 motion for leave to file a corrected preliminary statement accordingly is dismissed as moot.

Furthermore, had Morrison's § 1.635 motion for leave to rely on the new preliminary statement not been dismissed as moot, it would have been granted. The reasons given in Buschmann's motion to suppress for opposing Morrison's motion are not entitled to consideration, because they should have been presented in an opposition to that motion rather than in a motion to suppress. Compare Bayles v. Elbe, 16 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1990) (party whose motion was denied cannot present at final hearing reasons in favor of granting the motion which were not included in the original motion) (citing Fredkin v. Irasek, 397 F.2d 342, 346, 158 USPQ 280, 284 (CCPA), cert. denied, 393 U.S. 980, 159 USPQ 799

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<sup>42</sup> The March 15, 1988, date also precedes the earliest date given in Mannheimer's preliminary statement (paper No. 15), i.e., October 21, 1988.

(1968) (alleged lack of support for limitation in count 4 was not raised by a motion and the therefore is not entitled to consideration)). Also compare Koch v. Lieber, 141 F.2d 518, 520, 61 USPQ 127, 129 (CCPA 1944) (board need not consider new arguments at final hearing in support of motion to dissolve).

Furthermore, a motion to suppress is an inappropriate vehicle for challenging the corrected preliminary statement because motions to suppress concern the admissibility of evidence and a preliminary statement is not evidence. See § 1.629(e) ("A preliminary statement shall not be used as evidence on behalf of the party filing the statement.").

**E. Buschmann's motion to suppress Morrison's priority evidence**

For the following reasons, Buschmann's motion to suppress Morrison's priority evidence is dismissed or denied in all respects.

**1. The November 24, 1987, drawing (MX<sup>43</sup> 42)**

Buschmann's contention that the November 24, 1987, drawing is inadmissible is unconvincing for the reasons given above.

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<sup>43</sup> Morrison Exhibit.

## 2. Declaration testimony<sup>44</sup>

Buschmann's objections to the testimony of various witnesses as "hearsay" fail because the motion did not comply with the following requirements in the APJ's June 26, 1995, scheduling order<sup>45</sup> (at 13-14):

[A] motion by the senior party to suppress evidence must . . . explain where the evidence in question is relied on in the junior party's opening brief. A motion to suppress evidence as inadmissible hearsay must specifically identify the out-of-court statement in question and explain why it appears that the opponent is offering or intends to offer the statement itself (as opposed to related testimony) to prove the truth of the matter stated therein. [Original emphasis.]

Accordingly, the motion is dismissed as to these objections.

The objections to testimony about the November 24, 1987, exhibit (MX 42) fail because, as explained above, Morrison is entitled to rely on that drawing to establish the March 15, 1988, date alleged in his original preliminary statement. The motion is therefore denied as to these objections.

The objections for lack of foundation, i.e., personal knowledge, fail because the motion does not assert that, or

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<sup>44</sup> The item numbers and letters used herein correspond to those used in the motion to suppress (at 5-7).

<sup>45</sup> Paper No. 93.

explain why, these objections were not overcome by the witnesses' supplemental declaration testimony,<sup>46</sup> which was filed in response to Buschmann's written objections<sup>47</sup> under § 1.672(c) to the initial declaration testimony.<sup>48</sup>

**3. MX 42-44, 75, and 173, 174, and 175 [sic, 176]**

Buschmann objects to the notebook entries identified as MX 42-44 on the ground that they were allegedly made prior to the March 15, 1988, date given for the first drawing in Morrison's original preliminary statement. This objection fails for the reasons given above with respect to the testimony about MX 42. The motion is therefore denied as to these exhibits.

Buschmann objects on two grounds to MX 75, 173, 174, and 175 [sic, 176], which are ex parte declarations by Dr. Yue, Dr. Morrison, Maggie Taylor, and Scott P. Moen filed in Morrison's involved application Serial No. 07/875,530. The first ground is "hearsay," which fails for lack of compliance

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<sup>46</sup> Paper No. 112. This testimony appears in the Morrison Record at MR 154-95.

<sup>47</sup> Paper No. 100.

<sup>48</sup> Paper No. 97.

with the APJ's order. The second ground is that "no notice of intent to rely on [these] document[s] has been filed."<sup>49</sup> We assume, as does Morrison, that Buschmann is charging Morrison with failing to comply with § 1.671(e), which reads as follows:

(e) A party may not rely on an affidavit (including any exhibits), patent or printed publication previously submitted by the party under § 1.639(b) unless a copy of the affidavit, patent or printed publication has been served and a written notice is filed prior to the close of the party's relevant testimony period stating that the party intends to rely on the affidavit, patent or printed publication. When proper notice is given under this paragraph, the affidavit, patent or printed publication shall be deemed as filed under §§ 1.640(b), 1.640(e)(3), 1.672(b) or 1.682(a), as appropriate.

As Morrison correctly notes, this provision is inapplicable to the declarations in question because they were not submitted under § 1.639(c), i.e., in support of a motion, opposition, or reply.<sup>50</sup> The motion to suppress is therefore denied with respect to the alleged lack of notice.

**F. Should Count 5 be replaced?**

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<sup>49</sup> Motion at 7-8.

<sup>50</sup> As noted earlier, the interference rules as amended effective April 21, 1995, apply to the testimony stage of this interference. Prior to those amendments, § 1.671(e) required notice of intent to rely on ex parte affidavits and § 1.608(b) affidavits as well as on § 1.639(b) affidavits.

As noted earlier, Count 5 reads as follows:

A method of monitoring the condition of living tissue with a monitoring device comprising a radiation emitter sensor area and a radiation sensor area, said method comprising invasively sticking at least one sensor area into said tissue, emitting radiation from said radiation emitting [sic, emitter] sensor area to transilluminate tissue between the sensor areas, and monitoring the transillumination by means of said radiation sensor area.

Count 5 is virtually identical to Buschmann's claim 29, which the APJ held, and Buschmann does not dispute, is unpatentable over Kapany.<sup>51</sup> Specifically, the APJ held that because claim 29 is not limited to oximetry (pulse or non-pulse) and does not preclude two-dimensional imaging, it is unpatentable over Kapany on two grounds: (1) anticipation when the dual-probe apparatus of Kapany's Figure 7.16(b) is used in the intended manner, i.e., for generating a two-dimensional image; and (2) obviousness over the same apparatus when used to perform

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<sup>51</sup> Claim 29 reads as follows:

29. A method for monitoring the condition of living tissue with a monitoring device comprising a radiation emitter sensor area and a radiation sensor sensor [sic] area, said method comprising invasively sticking at least one sensor area into said tissue, emitting radiation from said radiation emitter sensor area to transilluminate tissue between the sensor areas, and monitoring the transillumination by means of said radiation sensor sensor [sic].



invasive spectrophotometric analysis of tissue, the obviousness of which was explained above.

Buschmann argues that "the count should not be interpreted as reading on [non-pulse] oximetry (even though it literally does), but should be construed as referring to pulse oximetry."<sup>52</sup> However, it is well settled that unambiguous counts are given the broadest reasonable interpretation without reference to either party's disclosure, DeGeorge v. Bernier, 768 F.2d 1318, 1321, 226 USPQ 758, 760-61 (Fed. Cir. 1985); Buschmann has not asserted, let alone demonstrated, that the count is ambiguous. See also Newkirk v. Lulejian, 825 F.2d 1581, 1583, 3 USPQ2d 1793, 1795 (Fed. Cir. 1987) (limitations not clearly included in a count should not be read into it). When the count is given its broadest reasonable construction, it does not require oximetry of any type, let alone specifically pulse oximetry. As a result, the count clearly encompasses unpatentable subject matter, i.e., the dual-probe arrangement shown in Kapany's Figure 7.16(b) when used either for two-dimensional imaging of tissue or for spectrophotometry (excluding oximetry) of tissue. The

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<sup>52</sup> B.Br. 108.

question remains whether and, if so, how count should be changed.

Mannheimer contends that Count 5 is also unpatentable over Kapany's teaching of performing I-I oximetry on tissue and that for this reason judgment should be entered against Buschmann's claim 28 on the ground of unpatentability and that the interference should be redeclared by replacing Count 5 with Buschmann's proposed O-I Count 2 and I-O Count 4, or with Mannheimer's proposed Count MAN-3, which recites these two species in the alternative.<sup>53</sup> Because, as explained above, Kapany does not suggest performing I-I oximetry on tissue, Mannheimer's request to replace Count 5 with Buschmann's proposed Counts 2 and 4 or with Mannheimer's proposed Count MAN-3 is denied. Furthermore, the absence of a request by Mannheimer to enter judgment with respect to the proposed counts suggests Mannheimer incorrectly believes that subsequent to such a redeclaration the parties would be permitted to present new priority evidence or new briefs with respect to the newly adopted counts. As the proposed counts were the subject of motions filed during the preliminary

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<sup>53</sup> Mann.Open.Br. 22.

motion period, the parties were required to present all of their evidence relevant to these counts during their testimony periods and to address that evidence and those counts in their briefs for this final hearing. Although Count 5 is unpatentable over Kapany's Figure 7.16(b) apparatus when used either for two-dimensional imaging of tissue or for spectrophotometry (excluding oximetry) of tissue, it is not necessary for us to determine what form an appropriate new count or counts should take because, as will appear, Morrison is not entitled to an award of priority even for a count as broad as Count 5. Nor is a determination of a new count or counts required so that an ex parte examiner, subsequent to termination of this interference, can apply the principles of res judicata, collateral estoppel, and interference estoppel with respect to any added or amended claims of the losing party. These determinations can be made with respect to the losing party's lost claims. See In re Deckler, 977 F.2d 1449, 1453, 24 USPQ2d 1448, 1450 (Fed. Cir. 1992) ("Deckler was not entitled to claims that were patentably indistinguishable from the claim on which he lost the interference.").

**G. The parties' positions on priority**

Senior party Buschmann stands on his March 24, 1988, German benefit date, which neither opponent has challenged at final hearing.

As junior party Mannheimer did not offer any priority evidence, judgment on the issue of priority is being entered infra against his claims that correspond to the count.

Regarding Morrison's case for priority, Buschmann concedes that Morrison achieved an actual reduction to practice on September 19, 1989,<sup>54</sup> which is eight months prior to Morrison's May 29, 1990, filing date. Morrison alleges conception in November 1987, an actual reduction to practice in February 1988, and diligence from prior to Buschmann's benefit date up to Morrison's filing date. Morrison also denies Buschmann's charge of abandonment, suppression, and concealment. Since Morrison's involved application is copending with Buschmann's involved application, Morrison's burden of proof is by a preponderance of the evidence. 37 CFR § 1.657(b).

Regarding the interference rules, the parties were

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<sup>54</sup> Brief at 43, ¶ 112.

advised by the APJ's scheduling order mailed June 26, 1995,<sup>55</sup> which set times for taking testimony and filing records and briefs, that the remainder of the interference would be governed by the interference rules as extensively amended effective April 25, 1995, citing Patent Appeal and Interference Practice -- Notice of Final Rule (hereinafter, 1990 Final Rule Notice), 60 Fed. Reg. 14,488 (March 17, 1995); 1173 Off. Gaz. Pat. & Trademark Office 36 (April 11, 1995). Thus, unless noted otherwise, all references to the interference rules are to the amended rules.

#### **H. Morrison's case for priority**

Morrison and Yue argue<sup>56</sup> that they are entitled to an award of priority because they conceived the invention prior to Buschmann's March 24, 1988, German benefit date, and achieved an actual reduction to practice in February prior to that date. Morrison and Yue also claim that their activity after the reduction to practice "neither lacked diligence nor was an abandonment, suppression or concealment of the

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<sup>55</sup> Paper No. 93, at 1.

<sup>56</sup> Morr.Open.Br. 56.

invention."<sup>57</sup>

Consequently, we construe Morrison and Yue's position to be that they are entitled to prevail on either of two grounds: (a) an actual reduction to practice prior to Buschmann's benefit date without abandoning, suppressing, or concealing or (b) conception prior to Buschmann's benefit date coupled with diligence during the critical period starting just before that date and ending on Morrison's actual filing date of May 29, 1990. However, in view of Buschmann's concession that Morrison achieved an actual reduction to practice on September 19, 1989, the critical period ends on that date rather than on Morrison's filing date. In our view, the eight-month interval between these dates is not long enough to raise a rebuttable presumption of suppression or concealment. Compare Schindelar v. Holdeman, 628 F.2d 1337, 1342-43, 207 USPQ 112, 117 (CCPA 1980), cert. denied, 451 U.S. 984, 210 USPQ 776 (1981) (two-year and five-month delay between reduction to practice and filing of application prima facie unreasonable).

Inasmuch as Morrison's corrected preliminary statement identifies Dr. Morrison and Dr. Yue as joint inventors of the

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<sup>57</sup> Morr.Open.Br. 69.

subject matter of the count, the testimony of neither of these witnesses can be relied on to corroborate the testimony of the other. Manny v. Garlick, 135 F.2d 757, 768, 57 USPQ 377, 388 (CCPA 1943).

**1. The November 24, 1987, designs as evidence of conception**

Morrison's earliest designs for a fetal pulse oximetry probe appear in MX 42, five pages of drawings and notes that Dr. Morrison made during a November 24, 1987, meeting which was also attended by co-inventor Dr. Yue and by the following Lake Region Manufacturing Company (hereinafter, Lake Region) personnel: Theodore Johnson, Joseph Fleischaker, Jr., Joseph Fleischaker, Sr., and Don Hanson.<sup>58</sup> Johnson, the only non-inventor witness who testified about this exhibit,<sup>59</sup> testified that he is certain this exhibit is an accurate copy of what Morrison prepared at that meeting.<sup>60</sup> This testimony is sufficient to establish

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<sup>58</sup> Johnson, MR 22, ¶¶ 3-6; MR 498:6-16.

<sup>59</sup> Hanson testified without mentioning this exhibit or the November 24, 1987, meeting. Neither of the Fleischakers testified.

<sup>60</sup> MR 493:18 to 494:19.

that the pages which form this exhibit were in existence on November 24, 1987, whether or not Johnson's testimony also demonstrates that he understood the contents of these pages at that time. Price v. Symsek, 988 F.2d 1187, 1195-96, 26 USPQ2d 1031,1037-38 (Fed. Cir. 1993).

Referring to page 1 of the exhibit, the sketch and notations in the upper part of the page corroborate J. Morrison's testimony that during the meeting he described a conventional fetal monitor having a single EKG lead for measuring the pulse rate.<sup>61</sup> The sketches and notations at the bottom part of the page corroborate his testimony that he also brought and demonstrated a conventional non-invasive pulse oximeter system having a clip-on probe for measuring oxygen saturation in a finger, ear, or nose using a visible red LED and an infrared LED for irradiating the tissue and a detector for receiving the transmitted radiation, with the detected infrared radiation intensity representing blood and the detected red radiation intensity representing blood + oxygen.<sup>62</sup>

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<sup>61</sup> J. Morrison, MR 77-78, ¶ 13.

<sup>62</sup> J. Morrison, MR 78, ¶ 14.



Page 2 of the exhibit discloses a "1st Generation Probe" or "Foxprobe" for "EKG + Oximeter + Temperature." The "Fox" in "Foxprobe" is derived from fetal oximetry.<sup>63</sup> This exhibit states that this probe is to have "Direct compatibility with Current fetal monitor" and "Direct compatibility with Conventional oximeters." The following notation also appears on this page:

"2 independent pulse rates - sort out artifacts  
Provides % O<sub>2</sub> saturation  
Monitors fetal temperature"

The "1st Generation probe," which is depicted in sketches at page 2 of the exhibit, consists of two separate parts connected together by a "coil + teflon sheath" containing "2 fibers + 4 wires." The first part of the probe contains "2 leds [light emitting diodes] + detector" and is connectable to a "Cable (wire)," presumably of conventional design. The second part of the probe is the "tip," which has two hypodermic "corkscrews," one for "Fiber + EKG" and the other for "Fiber + T.C." Although T. Johnson was unable to recall

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<sup>63</sup> J. Morrison, MR 78, ¶ 15.

what the term "T.C." represents,<sup>64</sup> it is apparent from the description of the "2nd Generation Probe" at page 4 as "EKG + Oximeter + ThermoCouple + pH" that T.C. refers to a thermocouple.<sup>65</sup> Pages 3 and 5 of the exhibit show that the "1st Generation Probe" can be formed as a disposable unit connectable by an adapter to a "Standard oximeter - Nellcor, etc." and to a "Conventional Fetal Monitor (EKG)."

Referring to page 4, as already noted, the "2nd Generation Probe" is described as being for "EKG + Oximeter + ThermoCouple + pH." The top sketch and associated notation indicate that pH is to be measured by light passing through a pH sensitive dye (HPTS), whose absorption characteristics are very pH sensitive. The bottom two sketches show that a hypodermic needle that contains, in addition to an "oximeter fiber," a chamber containing pH sensitive dye, a semi-permeable barrier wall for contact with the tissue, and two elements labeled "light in" and "light out," which Ted Johnson

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<sup>64</sup> MR 505:4-5.

<sup>65</sup> Ted Johnson's testimony corroborates the existence of the pages of this exhibit on November 24, 1987. It is not necessary for him to testify that he understood the contents of the drawing. See Price v. Symsek, 988 F.2d 1187, 1195, 26 USPQ2d 1031, 1037 (Fed. Cir. 1993).

explained are additional optical fibers for delivering light to and from the pH-sensitive dye chamber.<sup>66</sup> It is readily apparent from a comparison of the descriptions of the 1st and 2nd generation probes that the 2nd Generation probe necessarily includes a second hypodermic needle (not shown) which contains a second oximeter fiber, as Dr. Morrison testified.<sup>67</sup>

For reasons which will become apparent, it should be noted that each of the foregoing probe designs (hereinafter the November 1987 designs) employs a single probe tip supporting two hypodermic corkscrews supported in a fixed relationship and that these corkscrews contain the distal ends of optical fibers which are long enough to transmit light to and from LEDs and a detector contained in a separate housing.

We turn now to the question of whether the November 1987 designs demonstrate conception, which is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Burroughs Welcome Co. v. Barr Labs.,

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<sup>66</sup> T. Johnson, MR 510:17-24.

<sup>67</sup> J. Morrison, MR 81:6-7.

Inc., 40 F.3d 1223, 1227-288, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994), cert. denied, 515 U.S. 1130, 115 S.Ct. 2553 (1995)(citation omitted) (our emphasis). Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. Id. An idea that is in constant flux is not definite and permanent; conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it is to be used in practice. Burroughs Welcome, 40 F.3d at 1229, 32 USPQ2d at 1920. However, conception does not require a reasonable belief by the inventors that the invention would work for its intended purpose; the question is whether the inventors formed the idea of their invention in sufficiently final form that only the exercise of ordinary skill remains to reduce it to practice. Burroughs Welcome, 40 F.3d at 1231, 32 USPQ2d at 1922. Because the invention involves two different technological arts, i.e., fiber optics and pulse oximetry, the

sufficiency of the disclosure of Morrison and Yue's conception evidence must be judged from the standpoint of a person having ordinary skill in both arts. Compare In re Brown, 477 F.2d 946, 950-51, 177 USPQ 691, 694 (CCPA 1973) (where the invention involves two different technologies, the sufficiency of the disclosure is to be judged in terms of a person having ordinary skill in both technologies) (citing In re Naquin, 398 F.2d 863, [866,] 55 CCPA 1428 [158 USPQ 317, 319] (1968)). A conception must also include every feature of the invention recited in the count. Burroughs Wellcome, 40 F.3d at 1228, 32 USPQ2d at 1919 (citing Coleman v. Dines, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985)).

It is clear that the November 1987 designs represent embodiments of probes that Drs. Morrison and Yue envisioned as suitable for use in actual practice. It is also clear that these probe designs, if used as intended, will satisfy every limitation of method Count 5, as is necessary to prove conception. That is, the "radiation emitter sensor area" of the "monitoring device" recited in the count reads on the hypodermic needle and optical fiber that emit red and infrared light into the tissue under examination; the "radiation sensor

area" of the "monitoring device" reads on the hypodermic needle and optical fiber that receive red and infrared light from the tissue under examination. Moreover, the fact that both hypodermic needles are to be stuck into the tissue satisfies the requirement of the count for sticking at least one of the sensor areas invasively stuck into the tissue and emitting radiation from the radiation emitting sensor area to illuminate the tissue between the sensor areas. The question remains whether Morrison has also established by a preponderance of the evidence that at least one of those designs represents an operative invention. Burroughs Welcome 40 F.3d at 1227-288, 32 USPQ2d at 1919. As evidence of the operability of the November 1987 designs, Morrison cites tests carried out by Dr. Morrison in February 1988 and offered prove an actual reduction to practice.

**2. The alleged February 1988 actual reduction to practice**

Count 5 reads as follows:

A method of monitoring the condition of living tissue with a monitoring device comprising a radiation emitter sensor area and a radiation sensor area, said method comprising invasively sticking at least one sensor area into said tissue, emitting radiation from said radiation emitting [sic, emitter] sensor area to

transilluminate tissue between the sensor areas, and monitoring the transillumination by means of said radiation sensor area.

To establish a reduction to practice of a method count, it is first necessary to show that each step of the method was performed. Szekely v. Metcalf, 455 F.2d 1393, 1396, 173 USPQ 116, 119 (CCPA 1972).

Morrison and Yue's evidence of an actual reduction to practice consists of testimony about tests conducted by Dr. Morrison, and witnessed by his wife, Helen, an anesthetist.<sup>68</sup> These tests (hereinafter, the February 1988 tests) occurred on or about February 8, 1988, using the apparatus shown in the two photographs identified as MX 105.<sup>69</sup> Helen Morrison's testimony corroborates Dr. Morrison's testimony that the test apparatus used in these tests was made from a pair of 125 micron plastic optical fibers approximately one and one-half feet long, a pair of straight hypodermic needles, a Nellcor disposable tape-on finger probe (including read and infrared LEDs and a detector), and a Nonin pulse oximeter with a clip-

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<sup>68</sup> H. Morrison, MR 947:15.

<sup>69</sup> J. Morrison, MR 84-86, ¶¶ 24-25; H. Morrison, MR 148-50, ¶¶ 13-15.

on finger probe. The Nellcor probe was modified by exposing the two LEDs and the detector and using epoxy to bond one end of one fiber to the detector and one end of the other fiber to the two LEDs. The other end of each fiber was loosely<sup>70</sup> inserted into a respective hypodermic needle, with the end of each fiber extending slightly from the needle. Dr. Morrison then held both needles close together in his right hand between the thumb and forefinger<sup>71</sup> and inserted their ends through and under the skin of his left forearm such that the fiber ends were spaced apart about one or two millimeters while under the skin surface. Dr. Morrison explained that

[i]n this configuration, light was sent down one optical fiber from the emitter of the Nellcor probe and passed through the perfused tissue in my forearm and then the signal passed through the other optical fiber in my forearm to return through the detector of the Nellcor adult finger probe. This return optical signal was displayed on the Nonin oximeter monitor, which indicated that an acceptable level of oxygen saturation for an adult human, e.g., 97% to 100%, was measured. [MR 85, ¶ 25.]

Helen Morrison also mentions the presence of a motion artifact and gives the range as 95% to 100%: "Although there was a

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<sup>70</sup> J. Morrison,. MR 261:4-6.

<sup>71</sup> J. Morrison, MR 242:23 to 243:4.



considerable motion artifact, the oximeter responded accurately and displayed a normal range of saturation values, usually in the range of 95% to 100%." <sup>72</sup>

Helen Morrison also confirmed Dr. Morrison's testimony that he obtained the same results when he used a single hypodermic needle to insert the end of only the emitting fiber or the detecting fiber end under his skin and positioned the end of the other fiber on the skin. <sup>73</sup> She also explained that he used the apparatus to test tissue in other parts of his body, including

his leg, earlobes, hands, and fingers and obtained satisfactory oximetry readings. <sup>74</sup>

Buschmann argues that the February 1988 tests fails to qualify as an actual reduction to practice of the subject

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<sup>72</sup> H. Morrison, MR 148, ¶ 13.

<sup>73</sup> J. Morrison, MR 87, ¶ 31; H. Morrison, MR 149, ¶ 14.

<sup>74</sup> H. Morrison, MR 149, ¶ 14. Dr. Morrison further testified that he also successfully performed the test after bonding the optical fibers to a fetal finger probe to determine if the invasive fetal probe concept would work on a smaller size emitter and detector that forms the fetal finger probe (MR 86, ¶ 26). However, this testimony lacks corroboration and thus is entitled to no weight.

matter of the count for a number of reasons. The first is that the test apparatus was not "a monitoring device," as required by the count, because the emitter and the receiver were "constructed as separate devices; using a separate emitter and receiver would be impossible in practice and thus the 'monitoring device' of the count should be considered a single device."<sup>75</sup> We do not agree that the term "a monitoring device" as used in the count should be construed so narrowly. It is well settled that unambiguous counts are given the broadest reasonable interpretation without reference to either party's disclosure, DeGeorge v. Bernier, 768 F.2d 1318, 1321, 226 USPQ 758, 760-61 (Fed. Cir. 1985); Buschmann has not asserted, let alone demonstrated, that the count is ambiguous. See also Newkirk v. Lulejian, 825 F.2d 1581, 1583, 3 USPQ2d 1793, 1795 (Fed. Cir. 1987) (limitations not clearly included in a count should not be read into it). When the count is given its broadest reasonable construction, it does not require that the radiation emitter and the radiation detector be supported in a fixed relationship with respect to each other by a single carrier, i.e., probe body.

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<sup>75</sup> B.Br. 63-64, paragraph 5.

Nevertheless, we agree with Buschmann that the February 1988 tests failed to constitute an actual reduction to practice. They fail with respect to the November 1987 designs because the test apparatus did not employ the structure used in those designs, i.e., two hypodermic corkscrew needles containing optical fibers and supported in a fixed relationship to each other by a single probe body. The tests also fail as a simultaneous conception and reduction of practice of a probe design employing two nearly parallel, straight, separately supported hypodermic needles because there is no contemporaneous evidence demonstrating that Dr. Morrison and/or Dr. Yue contemplated using such an arrangement in the "complete and operative invention, as it is hereafter to be applied in practice," as is required for conception. Burroughs Welcome, 40 F.3d at 1227-288, 32 USPQ2d at 1919. Following the February 1988 tests, Dr. Morrison made no attempt to construct an probe tip employing straight needles; instead, he turned his attention to the problem of how to construct corkscrew hypodermic needles containing optical fibers. The first probe design by Morrison and Yue that did not employ at least one corkscrew hypodermic needle is the

design shown in MX 50, dated October 6, 1988, which employs a solid screw helix and two short hypodermic needles each having a single bend therein and containing an optical fiber.<sup>76</sup> As explained infra, probe designs employing straight hypodermic needles containing optical fibers were not conceived until the fall of 1989. See, e.g., MX 13, date stamped October 3, 1989, which shows a probe body 6 supporting a solid corkscrew needle 9 and an axially disposed straight hypodermic needle 10 which contains an optical fiber 1, which is the needle design that Buschmann concedes was actually reduced to practice on September 19, 1989.<sup>77</sup> No attempt was ever made to assemble a probe employing two straight hypodermic needles, as used in the February tests. Nor is such an arrangement disclosed in Morrison's involved application.

For the foregoing reasons, we conclude that the February 1988 test apparatus, rather than being envisioned as an embodiment of a complete and operative probe as it would be thereafter applied in practice, instead was simply designed to determine the feasibility of using hypodermic needles

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<sup>76</sup> T. Johnson, MR 32, ¶ 26.

<sup>77</sup> B.Br. 43, ¶ 112.

containing optical fibers to carry red and infrared light to and from a region of tissue whose oxygen saturation is to be measured.

**3. The alleged problems with the February 1988 test apparatus and the November 1987 designs**

Although our holding that the February 1988 test apparatus did not represent an embodiment of a complete and operative probe as it would be thereafter applied in practice is reason enough to deny Morrison's claim of a February 1988 actual reduction to practice, we have also considered Buschmann's alternative argument that the February tests fail as an actual reduction to practice because the test apparatus was not actually measuring oxygen saturation. Dr. Morrison gave the following reasons for his confidence that the February 1988 test apparatus actually measured the oxygen saturation of the arterial blood in his forearm tissue:<sup>78</sup>

27. . . . First, oximeter monitors are designed and constructed such that the oximeter probe to which they were connected would provide me a legitimate saturation reading, or no reading at all. The nature of the electronic instrumentation is that it will not give you a reading unless it is measuring saturation since the oximeter is designed to avoid artifacts. If the oximeter senses that the optical signal passing through the

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<sup>78</sup> MR 86: ¶ 27.

optical fibers includes too many artifacts, then the oximeter monitor will display no reading at all.

28. When measuring oxygen saturation, the oximeter monitor waits until it identifies measurements of four to eight legitimate pulses (heart beat pulses) resulting from the pulsatile variations in the perfused tissue. Once the oximeter monitor identifies a sufficient number of legitimate pulsatile signals, then the oximeter monitor displays a pulse (heart rate) and oxygen saturation.

29. When I performed the tests with the invasive fetal probe configuration, with one or both needles (with optical fibers therein) under my skin, the oximeter monitor connected to my probe first "beeped " multiple times, indicating identification of legitimate pulsatile signals before displaying an oxygen saturation and pulse (heart rate) reading. Since the oximeter monitor operated in the fashion it normally does when measuring oxygen saturation, I was confident that the optical fiber arrangement under my skin was measuring oxygen.

30. Second, about the same time I performed the test, I also measured the oxygen saturation of my finger using a conventional non-invasive pulse oximetry probe. The oxygen saturation measured at my finger with a conventional probe closely approximated the oxygen saturation measured in my forearm with the invasive fetal probe design. Exhibit 106 is a true and accurate copy of a color photograph of the finger probe I used during this testing period. [Emphasis added.]

The Morrison reply brief further argues<sup>79</sup> that "[i]t is quite unlikely that pulse oximeter monitoring manufacturers would let a pulse oximeter monitor be sold publicly that did not prevent a false reading based on motion artifact (by evaluating the signal coming in as either legitimate or not

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<sup>79</sup> Morr.Open.Br. 36.

legitimate) and either give no reading at all, or give a standard error alert reading."

Buschmann has presented evidence which persuades us that the foregoing assumptions are incorrect, i.e., that the test apparatus was actually responding to stimuli other than the oxygen saturation of the arterial blood in Dr. Morrison's forearm tissue. Buschmann also uses this evidence to demonstrate the inoperability of the, in which case they fail as proof of conception.

Buschmann's evidence of inoperability consists of testimony by inventor Dr. Buschmann<sup>80</sup> and by Reinhold Falkowski concerning various tests they performed<sup>81</sup> which allegedly revealed the following problems with the February 1988 test apparatus:

**(a) Shunt light**

Buschmann uses the term "shunt light" to refer to DC red and infrared light that travels directly from the LEDs to the photodiode without passing through the optical fibers and

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<sup>80</sup> Cited at B.Br. 78.

<sup>81</sup> Cited at B.Br. 60, 74-75. Falkowski is employed by BLM (Falkowski, BR 21), which was founded by Dr. Buschmann in 1978 (Buschmann, BR 7, ¶ 2).

tissue.

DC red and DC infrared are two of the quantities detected by an oximeter and used to calculate omega (**S**), the other two values being AC red and AC infrared:<sup>82</sup>

$$\mathbf{S} = \frac{\text{AC}_{\text{red}}/\text{DC}_{\text{red}}}{\text{AC}_{\text{IR}}/\text{DC}_{\text{IR}}} = \frac{\text{MD}_{\text{red}}}{\text{MD}_{\text{IR}}}$$

The relationship between omega and oxygen saturation is represented by the graph at page 12 of Buschmann's brief.

Falkowski testified<sup>83</sup> that when he constructed the Morrison test apparatus without using glue to connect the ends of the optical fibers to the LEDs and photodiode of the modified Nellcor finger probe, he measured shunt light values of 18 nW red and 33 nW infrared, whereas when he placed a black absorbing hard foam between the emitter and receiver, he obtained values of 0 mV [sic, nW] red and 0 mV [sic, nW] infrared. These 18 nW (red) and 33 nW (infrared) values are much higher than the 3 nW of light that Falkowski measured as passing through the tissue under "optimal coupling

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<sup>82</sup> B.Br. 12.

<sup>83</sup> BR 24.



conditions," which appears <sup>84</sup> Falkowski found that the amount of shunt light increases dramatically when glue is used to connect the optical fibers to the LEDs and photodiode and that the magnitude of the increase depends on the material used and its absorbing and scattering properties, with a factor of ten not being a bad guess.<sup>85</sup> Morrison responds that Falkowski failed to take into account the fact that Dr. Morrison protected against shunt light by using lumps of opaque epoxy,<sup>86</sup> citing "Morrison J., MR 257-60, and Inspection of Exhibit 105, 232, 234 (see MR 27[1]-272), Exhibit 235."<sup>87</sup> However, the cited testimony does not describe the epoxy as opaque, which in any event seems an unlikely choice for a material that is to provide optical coupling. Nor does the adhesive in Exhibits 232 and 234 appear to be opaque, although some parts of the surface appear very dark, which could be the result of aging -- these photos apparently were not taken until after

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<sup>84</sup> BR 25-26, ¶ 4d.

<sup>85</sup> BR 53:1-32.

<sup>86</sup> Morr.Open.Br. 33.

<sup>87</sup> Morr.Open.Br. 33.

the interference was declared.<sup>88</sup> Morrison also argued that the tests were performed in a darkened room so as to further guard against unwanted light paths and contamination.<sup>89</sup> Falkowski's tests also were unaffected by ambient light, as he detected no red and infrared shunt light with the black absorbing foam in place.

Falkowski's testimony persuades us it is likely that during the February 1988 tests the oximeter was responding at least in part to red and infrared shunt light, which would have been incorrectly treated as  $DC_{red}$  and  $DC_{IR}$  by the oximeter. As is clear from the equation for  $\omega$  and the chart showing the relationship between  $\omega$  and oxygen saturation, the effect of shunt light on the displayed saturation value depends on the relative levels of amounts shunt red and shunt infrared. An increase in shunt infrared ( $DC_{IR}$ ) increases  $\omega$  and decreases saturation; an increase in

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<sup>88</sup> During Dr. Morrison's cross-examination, counsel Grunzweig stated that he observed the taking of these photographs. MR 271:21-25.

<sup>89</sup> Id.

shunt red ( $DC_{red}$ ) decreases omega and increases saturation.<sup>90</sup>

For all omegas at or below 0.4, the saturation is given as 100%.

We agree that shunt light likely contributed to incorrect oxygen saturation readings during the February 1988 tests and that for this reason those tests do not constitute an actual reduction to practice even if the February 1988 test apparatus represented an embodiment of a complete and operative probe as it would be thereafter applied in practice. However, this does not detract from the operability of the November 1987 designs, because one having ordinary skill in the art presumably would have known to shield against shunt light. An inoperative disclosure can be relied on to prove conception "if the invention can readily rendered operative without the exercise of the inventive faculty." See I C.W. Rivise & A.D. Caesar, Interference Law & Practice § 120, at 355-60 and cases cited therein (Michie Co. 1940).

**(b) Insufficient light to the tissue site**

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<sup>90</sup> Falkowski incorrectly asserts that "[i]f DC infrared has a greater shunt than DC red, the ACs being indifferent around one, omega becomes smaller than 1 and the saturation accordingly is displayed as being in the upper range" (BR 32, last three lines).

Falkowski testified<sup>91</sup> that

Dr. Morrison stuck two hypodermic needles parallel into the tissue, fed the emitting and receiving fibers into the hypodermic needles until they touched the tissue and finally optionally removed the fiber. Thus, he positioned the ends of the optical fibers 1 mm apart having tissue between the ends of the fibers. When we repeated the experiment here, we got under optimal coupling conditions less than 3 nW through the tissue. This is the resolution lower limit of our big R & D pulse oximetry device.

By "lower limit" Falkowski apparently means the minimum acceptable amplitude for modulated (i.e., AC and DC) red and infrared light components produced when actually measuring the transmission of light through pulsatile tissue. Falkowski further explained<sup>92</sup> that

From additional experiments we guess that the light intensity was not even 300 FW [sic, FFW]. If this is compared to the shunt light of 18 nW respectively 33 nW [sic, 18 nW red and 33 nW infrared], the DC [shunt light] is in the range of 60 to 100 fold that of the light transmitted through the tissue. . . .

While Morrison faults Falkowski's tests for using steak instead of live tissue,<sup>93</sup> he did not explain, and it is not apparent to us, why this would invalidate the foregoing test

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<sup>91</sup> BR 25-26, ¶ d.

<sup>92</sup> BR 26, ¶ e.

<sup>93</sup> Morr.Open.Br. 37.

results. Furthermore, Falkowski's tests results are consistent with subsequent tests allegedly conducted by Dr. Morrison. Specifically, on October 18, 1988, Dr. Morrison, using a low power calibrated wave length power meter obtained from Newport Corporation,<sup>94</sup> found that the 125 micron optical fibers he used in the February 1988 tests were not carrying enough light:<sup>95</sup>

After testing the optical power and sensitivity of the 125 micron optical fiber, I believed I wasn't getting enough light in or out of the fiber. Accordingly, in my notebook entry of October 18, 1988 (Exhibit 136) I noted that I would make a new probe configuration using 250 micron optical fiber. . . .

On November 8, 1989, Morrison conducted tests on probe that Ted Johnson had made having an optical fiber inside a spiral needle and recorded the test results in a page (MX 128) in his research notebook.<sup>96</sup> This notebook page, which is dated "11/8," shows a light output of about 18 nW for a twisted

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<sup>94</sup> J. Morrison, MR 99, ¶ 69.

<sup>95</sup> J. Morrison, MR 102, ¶ 75. Although this testimony is uncorroborated, it can be relied on as an admission against interest. Gruber v. Via, 221 USPQ 276, 279 (Bd. Pat. Int. 1982); Wagner v. Notley, 202 USPQ 299, 303 (Bd. Pat. Int. 1977) (citing III C.W. Rivise and A.D. Caesar, Interference Law and Practice § 402 (Michie Co. 1947)).

<sup>96</sup> J. Morrison, MR 106, ¶ 88.

fiber versus about 270 nW for a straight fiber. A second test shows about 18 nW for a twisted fiber versus about 210 nW for a straight fiber.

Finally, in the summer of 1989, testing of probes Mayall made with a dual spiral configuration and others he made with a single coil containing a fiber and a center cannula containing a fiber showed that their performance was "marginal" and that it was necessary to increase the overall optical efficiency, which was accomplished by switching to two designs having the LEDs directly on the face of the probe tip.<sup>97</sup> In one design, light was collected by an optical fiber in a coiled needle (see MX 12, page 1); in the other, light was collected by an optical fiber in a central cannula (MX 13, page 1). It is the latter design that Buschmann concedes was actually reduced to practice on September 19, 1989.<sup>98</sup>

In view of the above, we hold that Morrison failed to demonstrate that the February 1988 test apparatus delivered enough light to the tissue site to result in a valid oxygen saturation reading. As a result, the February 1988 tests

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<sup>97</sup> Mayall, MR 141-42, ¶ 12.

<sup>98</sup> B.Br. 43.

failed to constitute an actual reduction to practice even if the test apparatus represented an embodiment of a complete and operative probe as it would be thereafter applied in practice. Because the November 1987 designs employ optical fibers in needles (coiled needles at that) to deliver light to the tissue site, those designs also would deliver insufficient light to the tissue site and thus are ineffective as evidence of conception.

**(c) Motion artifacts due to needle movement**

According to Falkowski, the only explanation possible for obtaining apparently valid pulse rate and oxygen saturation readings with the February test apparatus is that<sup>99</sup>

all of the light going through the fibers has been modulated by motion artifacts and thus became AC of the Morrison experiment. The corresponding DC is the shunt light traveling from one drop of glue to the other drop of glue. Thus, he [Morrison] encountered a modulation depth of about 1% to 2% which is a normal modulation depth for a commercial pulse oximeter, if the waveform happens to look like a pulse.

Falkowski then explained how this must have happened:<sup>100</sup>

Experimentally, we found that [when] keeping the two hypodermic needles perpendicular to the skin, as Dr.

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<sup>99</sup> BR 26, ¶ e.

<sup>100</sup> BR 26, ¶ f.

Morrison described the experiment, the researcher's finger pulse creates a pulsatile motion artifact. In the absence of noise, i.e., when Dr. Morrison happened to keep the needles so steady that only his finger pulse was taken up, he happened to create an acceptable signal.

Specifically, this finger pulse caused variations in the spacing of the needle tips:<sup>101</sup>

[I]t is obvious that the pulse he detected was his own pulse, but the origin was not the arterial blood moving in an out (= arterial pulse) but a motion artifact, i.e. a changing distance between two fiber tips creating a changing pulse length through tissue with all the components present, tissue, venous blood, capillary blood, arterial blood while only the arterial blood should change (optical plethysmography).

This argument has support in the following test conducted by Falkowski, which he offered in support of the argument, discussed infra, that a needle spacing of 1 or 2mm of tissue is too close to provide a detectable modulation signal even under optimal coupling conditions, i.e., without using optical fibers.

Although Falkowski does not so state, Morrison<sup>102</sup> appears to accept Buschmann's claim<sup>103</sup> that this test was performed on a

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<sup>101</sup> BR 31, ¶ 11.

<sup>102</sup> Morr.Open.Br. 37.

<sup>103</sup> B.Br. 75; Buschmann, BR 19, ¶ 27.



piece of steak rather than on living tissue. The test was conducted as follows:

In order to get rid of the problems with optical fibers, I replaced the optical fibers by the semiconductors itself placing the semiconductors inside tiny windows in straight hypodermic needles which I covered with a transparent epoxy adhesive. Thus, I had one emitting needle and one receiving needle which I could stick into the tissue with any distance desired. Since I had no light losses coupling the light into fibers, I had plenty of light and an excellent signal quality accordingly. Given this ideal experimental conditions I could concentrate on the biological background: The modulation depth of a very small tissue layer. I stuck in the two hypodermic needles at a distance of 2.0 mm using a precise carrier keeping the distance constant while inserting the needles. After the needles were positioned I gave the needles free, so that they could pulsate freely like the hypodermic needles in the original Morrison experiment. In this experiment with 2 mm tissue layer I measured an AC to DC ratio (= modulation depth) of 0.03% in the red and 0.04% in the infrared. Since Dr. Morrison had only 1 mm I repeated the experiment with a gap of 1 mm tissue layer. Here I received a modulation depth of 0.015% for the red and 0.02% for the infrared. This is an irrefutable proof that the Morrison experiment did not work in the sense that the values displayed had nothing to do with pulse oximetry. Any commercial pulse oximeter would have given a low perfusion error message receiving such a low modulation depth. Even if Dr. Morrison had had access to such sophisticated sensors we are able to build now after years of work and experience in building invasive sensors which Dr. Morrison has not had [sic] at that time, he could not have received a reasonable signal on a commercial pulse oximeter.

We understand Falkowski's statement that he "gave the needles free, so that they could pulsate freely like the hypodermic

needles in the original Morrison experiment" to mean that he held the needles between his thumb and index finger, as Dr. Morrison did. As a result, this test demonstrates that the heartbeat in Falkowski's thumb and index finger caused some light modulation, albeit at levels slightly below the minimum levels required by a conventional oximeter (i.e., 0.05 to 0.07%<sup>104</sup>). In fact, Dr. Morrison admitted that some needle spacing variations may have occurred, though he doubted they were detectable. Specifically, when asked whether this modulation of the needle distance could have created a pulse artifact,<sup>105</sup> he responded:<sup>106</sup>

It may be possible, but it would not be expected to produce a normal kind of saturation. It would be detected as perhaps a pulse, but generally not reported by the oximeter as a valid saturation reading unless you could be extremely consistent about the motion artifact thus produced.

Q. Isn't the pulse in your thumb a consistent pulse?

A. Yeah, but you have to have a consistent pulse, you have to have consistent pressure, consistent spacing between the ends of the needles. There are too many factors that must remain consistent for you to

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<sup>104</sup> BR 27, ¶ 6.

<sup>105</sup> J. Morrison, MR 18-20.

<sup>106</sup> J. Morrison, MR 254:5 to 255:11.

obtain a saturation reading because of the motion artifact. That's been my experience.

We are of the view that even if, as Morrison contends, the test apparatus actually was measuring the oxygen saturation of the arterial blood in Dr. Morrison's forearm tissue, the light modulation caused thereby may have been significantly affected by the light modulation due to the variations the distance between the needle ends, which is sufficient reason to doubt the accuracy of the oxygen saturation readings. Consequently, this is an additional reason why the February tests did not constitute an actual reduction to practice. However, this problem does not make the November 1987 designs inoperative, because in those designs the distance between the ends of the needles is fixed.

**(d) Motion artifacts due to fiber optic movement**

Falkowski also testified<sup>107</sup> that when optical fibers are bent, the light intensity is modulated as the fiber's geometry changes, and that this effect plays a significant role

if the accuracy of the light transmission is high, i.e., if modulation of 1% or less is a problem. This is exactly the case in pulse oximetry, since a modulation in the range of 0.1-1% is exactly the AC signal range.

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<sup>107</sup> BR 29-30, ¶ 10.

Accordingly light fibers are inadequate for pulse oximetry, at least to the degree where movement of the fiber can not be securely excluded.

As evidence that movement of an optical fiber is capable of modulating light that is being transmitted therethrough, Falkowski<sup>108</sup> cites Buschmann's U.S. Patent 5,241,300 (BX 1), which discloses an infant vest which operates on this principle to monitor respiration.

However, Falkowski did not present any experimental proof that this was a significant problem in the February 1988 test apparatus. Nor it apparent why the probe employed in the September 19, 1989, actual reduction to practice, which had a long optical fiber for transmitting received light from the tissue site to a remote photodetector, did not also suffer from this problem. We therefore are not persuaded that the February 1988 test apparatus or the November 1987 designs were inoperative in this respect.

**(e) Wavelength mismatch**

Buschmann argues<sup>109</sup> that the results of the February 1988 tests are suspect because the Nonin oximeter was not

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<sup>108</sup> BR 29-30, ¶ 10.

<sup>109</sup> B.Br. 68-69.

calibrated for use with a Nellcor finger probe, which may have employed different radiation wavelengths than were used to calibrate the oximeter. We find this argument unpersuasive in view of the testimony by Helen Morrison, an anesthetist, that it was her understanding that "[m]any probes can adapt to different pulse oximeters"<sup>110</sup> and that she was personally aware of hospital personnel using a Nellcor probe with a Nonin oximeter.<sup>111</sup> Moreover, Buschmann's argument is not supported by any data establishing an actual wavelength mismatch between Nonin oximeter and the Nellcor finger probe. The argument concerning the alleged wavelength mismatch is therefore unconvincing with respect to the alleged February 1988 actual reduction to practice as well as the alleged November 1987 conception. Furthermore, even if it assumed that wavelength mismatch caused significant errors in the oxygen saturation readings obtained during the February 1988 tests, this would not undercut the claim of conception, because one having ordinary skill in the oximetry art would have recognized this problem and would have known to avoid it.

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<sup>110</sup> H. Morrison, MR 946:22-23.

<sup>111</sup> H. Morrison, MR 947:3-6.

**(f) Insufficient tissue thickness**

Falkowksi offers both a theoretical explanation and an experiment which allegedly prove that a needle tip spacing of 1-2 mm of tissue is too small to yield provide a detectable modulation signal. The theoretical explanation<sup>112</sup> is that a finger sensor used on a tissue layer 10 mm to 15 mm thick results in a modulation depth of about 1% to 5%, that decreasing the thickness by a factor of 5 decreases the modulation depth by a factor of 5 or even more, and that decreasing the tissue thickness to 1 mm will result in a modulation depth below the 0.05% to 0.07% minimum modulation depth accepted by commercial pulse oximeters. This argument is unconvincing for the following reason. Taking the worst case of a 1% modulation depth for 15 mm of tissue, the modulation depth for 1 mm of tissue (the lower end of the 1-2 mm range given by Dr. Morrison) would be 1% divided by 15, or 0.067%, which is within the minimum acceptable modulation range of 0.05% to 0.07%. For 1.5 mm of tissue, the modulation would be 1% divided by ten, or 0.1%, which is above the minimum acceptable modulation range. The experiment on which

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<sup>112</sup> BR 27, ¶ 6.

Falkowski relies is the "steak" experiment described above under the heading "Motion artifacts due to needle movement," in which Falkowski measured modulation depth of 0.03% (red) and 0.04% (infrared) for a 2 mm needle tip spacing and 0.015% (red) and 0.02% (infrared) for 1 mm. As noted above, this test demonstrates that the heartbeat in Falkowski's thumb and index finger caused light modulation at levels too small to be detected by a conventional oximeter when the needles ends were 1-2 mm apart in a piece of steak., The test does not show that this spacing is too small when the needles ends are 1-2 mm apart in live tissue.

For the foregoing reasons, we are not persuaded that Morrison's February 1988 test apparatus was inoperative for failing to employ a sufficiently large spacing between the needle ends or that the November 1987 designs were inoperative for that reason.

**(g) Failure to test over a range of saturation values**

Buschmann argues that the February 1988 tests fail to show that the test apparatus would work in its intended environment, because it was not used to track changes in

oxygen saturation levels or to detect any abnormal oxygen saturation level, such as a level below 80%, which Dr. Morrison conceded is essential in a useful oximeter:<sup>113</sup>

Q. In order for an oximeter to be considered operating properly, isn't it true that it would be necessary for it to respond down to a range of at least 80 percent?

A. I don't believe that would be sufficient.

Q. It would have to go lower than 80 percent?

A. Yes, in my opinion.

See also MR 268:8-11, where Dr. Morrison explained that "to the best of my knowledge, commercially used oximeters do go below 80 percent. If they didn't, they wouldn't probably be useful."

Curiously, Buschmann did not make this argument with respect to Dr. Morrison's September 19, 1989, test, which Buschmann concedes constituted an actual reduction to practice.<sup>114</sup> That test, which was recorded on videotape by

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<sup>113</sup> J. Morrison, MR 267:15-21.

<sup>114</sup> B.Br. 43, ¶ 112.



Helen Morrison,<sup>115</sup> involved a probe like that shown in the drawing at the seventh page of MX 173, which has a solid wire coil, LEDs mounted on the face of the probe tip, and a center cannula containing an optical fiber.<sup>116</sup> The videotape shows that with this probe screwed into Dr. Morrison's finger tip, oximeter showed readings between \_\_\_ and 100%. In any event, since the oximeter was conventional and thus known to be capable of tracking AC<sub>red</sub>, DC<sub>red</sub>, AC<sub>IR</sub>, and DC<sub>IR</sub> for arterial blood over the required range of oxygen saturation values, it was not necessary for Dr. Morrison to reprove that capability. It was only necessary to prove that the AC<sub>red</sub>, DC<sub>red</sub>, AC<sub>IR</sub>, and DC<sub>IR</sub> values obtained when using his test apparatus actually represented the arterial blood in the tissue between the needle ends, which he failed to do for the reasons noted above. Therefore, Dr. Morrison's failure to use the February 1988 test apparatus over a range of saturation values does not

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<sup>115</sup> MX 72; J. Morrison, MR 124, ¶ 149; H. Morrison, MR 150, ¶ 17.

<sup>116</sup> This drawing, which is undated, indicates that it was witnessed and understood by Helen Morrison. A different copy of the same drawing, witnessed by someone else on September 30, 1989, is in the record as MX 13, which Morrison's attorney, Clayton Johnson, received from Dr. Morrison on October 3, 1989 (C. Johnson, MR 11, ¶ 30).

detract from

the alleged February 1988 actual reduction to practice.

Furthermore, that argument is irrelevant to conception.

**(h) Summary**

The February 1988 tests fail as an actual reduction to practice of the method recited in Count 5 because Morrison has not demonstrated that the oximeter readings were not responding to significant amounts of the following factors:

(a) shunt light;

(b) Insufficient light to the tissue site; and

(c) Motion artifacts due to needle movement.

Of these factors, (b) and (c) also apply to the November 1987 designs and thus render them insufficient to prove conception of the subject matter of Count 5.

If Count 5 were replaced by proposed Buschmann Counts 2 and 4 or by proposed Mannheimer Count MAN-2, which are limited to the I-O and O-I species of invasive tissue oximeters, the November 1987 and February 1988 tests would fail as evidence of conception and an actual reduction to practice for the additional reason that they represent I-I species and thus

would fall outside the count.

**5. Additional alleged problems  
with the November 1987 designs**

Buschmann questions the sufficiency of the disclosure of the November 1987 designs (MX 42) in a number of respects, including the following:<sup>117</sup>

If there are 2 fibers, one fiber would have to transmit both red and infrared light. There is no disclosure of how to feed both red and infrared light into a single fiber. There is no discussion of how to modify the signal analysis software for the signal processor. There is no discussion of how to make this probe (and in fact they were never able to make this probe). Further, the discussion of technique is incorrect - one does not measure two independent pulse rates.

The criticism that the conception document does not explain how

to feed both red and infrared light into a single optical fiber is unconvincing, because it fails to take into account that the sufficiency the disclosure is to be judged from the standpoint of a person skilled in both fiber optics and pulse oximetry.

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<sup>117</sup> B.Br. 20, ¶ 37.

Buschmann has not satisfactorily explained why such an artisan would have required undue experimentation to couple a single optical fiber to two LEDs.

Insofar as software design is concerned, Buschmann has not satisfactorily explained why the November 1987 designs, which were intended to be issued with a conventional oximeter, would require any modification of the software used by the oximeter, let alone why such modification would require undue experimentation.

As for the absence of any discussion in MX 42 of how to make probes disclosed therein, the question of whether the designs depicted could have been made operable by one skilled in the art was addressed, supra.

Regarding the "two different pulse rates" mentioned in the exhibit, it is not clear to us from the record what this phrase means. However, even assuming for the sake of argument that pulse oximetry does not employ two different pulse rates, Buschmann has not explained why the artisan would have failed to recognize this error or would have been so misled by this error as to have required undue experimentation to make the probes in question.

**6. The March 15, 1988, design as  
proof of conception**

As the November 1987 designs and February 1988 tests are insufficient to establish conception or an actual reduction to practice, it is necessary to consider whether the design depicted in the drawings dated March 15, 16, and 21, which are prior to Buschmann's March 24, 1988, benefit date, constitutes a conception. These drawings (MX 45-48), which were made by Ted Johnson, showing a different fetal probe design that is hereinafter referred to as the March 15, 1988, design. MX 47 is a copy of a page dated March 16, 1988, from Johnson's Lake Region notebook,<sup>118</sup> witnessed by Hanson at the time it was made,<sup>119</sup> and containing three sketches. The top sketch, labeled "PRESENT DESIGN," shows a plastic, cylindrical fetal probe body having a .022" s.s. (stainless steel) cork screw extending one from face and two twisted leads extending from the other. Although Ted Johnson explained that this sketch represents a market device which was not used for

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<sup>118</sup> T. Johnson, MR 29, ¶ 20.

<sup>119</sup> Hanson, MR 42, ¶ 4.

oximetry,<sup>120</sup> he did not explain what it was used for. [We note that a fetal probe having this construction is described in the "Background Art" portion of Hochberg (col. 1, lines 29-39) as useful for measuring fetal heart rate, i.e., an EKG.]

The middle sketch in MX 47, labeled "NEW FIBER OPTIC DESIGN, employs fiber optics in place of the two twisted leads. As is apparent from this sketch, the distal end of a first optical fiber extends axially through the probe body, terminating at the distal face. As shown in both the middle and bottom sketches, the distal end of a second optical fiber extends through the probe body and through the center of the cork screw, which is hollow and may be formed of metal or plastic. Notation to the right of the bottom sketch states that "FIBER IN CORKSCREW CAN BE FOR PH. FIBER ON HUB SURFACE CAN DETECT PULSE." The same design, dated 3/16/88, appears as the bottom sketch in MX 45, which is a copy of a page from Ted Johnson's personal notebook,<sup>121</sup> and also in MX 46, a detailed drawing

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<sup>120</sup> T. Johnson, MR 576:1-10.

<sup>121</sup> T. Johnson, MR 28, ¶ 19.

made by Ted Johnson on March 15, 1988.<sup>122</sup> The same design also appears in a drawing (MX 48) made by Ted Johnson on March 21, 1988,<sup>123</sup> which is the last drawing dated prior to Buschmann's March 24, 1988, benefit date.

As Buschmann correctly notes,<sup>124</sup> although these sketches and the accompanying notation identify the straight axial optical fiber as a "pulse fiber" or a "pulse monitoring fiber," there is no mention of pulse oximetry, measuring oxygen saturation, or having a separate emitter and receiver. Nor is there any explanation in the exhibits of how the optical fiber in the corkscrew hypodermic needle is to measure pH. Ted Johnson testified that when he made the sketch identified as MX 46, he understood it to "illustrate hypodermic tubing embedded in a plastic probe to form a hollow corkscrew needle and to form a straight needle."<sup>125</sup> He also offered the following explanation of how the March 15, 1988, design was to be used to measure oxygen saturation:

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<sup>122</sup> T. Johnson, MR 570:1-14.

<sup>123</sup> T. Johnson, MR 574:23 to 575:18.

<sup>124</sup> B.Br. 22, ¶ 43.

<sup>125</sup> T. Johnson, MR 570:1-14.

While I understood that this configuration (having two optical fibers arranged for placement below the fetal skin and spaced from each other) was for pulse oximetry, i.e., measuring fetal oxygen saturation, I also understood that one of the optical fibers could be used to measure the pH, in addition to pulse oximetry, along the lines of the Second [G]eneration design shown in Exhibit 42.<sup>126</sup>

Johnson's explanation of the March 15, 1988, design is unconvincing for several reasons. First, when he was asked during cross-examination to explain how this design would monitor oxygen saturation, he replied that he did not know.<sup>127</sup> Second, none of the documents disclosing the March 15, 1988, design employ any of the language used in the November 24, 1987, exhibit (MX 42) to indicate that oxygen saturation is to be measured, i.e., the language "Oximeter" (pp. 2, 4), "Provides % O<sub>2</sub> saturation" (p. 2), and "oximeter fiber" (bottom of p. 4). Instead, the March 15, 1988, design documents employ the term "pH," which is clearly distinguished from oximetry in the notations about the "2nd Generation" probe. Third, the drawings of the March 15, 1988, design do not show enough optical fibers to measure pH and oxygen

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<sup>126</sup> T. Johnson, MR 27-28, ¶ 18.

<sup>127</sup> T. Johnson, MR 576:14-16.



saturation in the manner of the "2nd Generation" probe, which employed a total of four optical fibers, three in a first hypodermic needle, of which two are used to measure pH and the third is used to measure oxygen saturation in cooperation with a fourth fiber contained in a second hypodermic needle. The sketches of the March 15, 1988, design clearly show a total of two optical fibers, of which MX 47 indicates that the "FIBER IN CORKSCREW CAN BE FOR PH" and the "FIBER ON HUB SURFACE CAN DETECT PULSE."<sup>128</sup> As a result, we are not persuaded that the March 15, 1987, probe design was intended to be used to measure oxygen saturation by pulse oximetry. It is possible that this design instead represents a probe for measuring pH and pulse rate (i.e., heartbeat), albeit in a manner that is not apparent to us. Consequently, the March 15, 1988, design does not represent a conception. We note in passing that Buschmann's contention<sup>129</sup> that "the drawings [of the March 15, 1988, design] refer to one optical fiber for pulse and another optical fiber for pH (apparently similar to Hochberg)" (our

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<sup>128</sup> Notation adjacent to bottom sketch on MX 47.

<sup>129</sup> B.Br. 21-22.

emphasis) inaccurately characterizes Hochberg,<sup>130</sup> which uses both of its optical fibers (30 and 32) to measure pH. Hochberg uses wires 22 and 24 to measure EKG, i.e., the fetal pulse rate.

Assuming for the sake of argument that Ted Johnson's testimony about using the March 15, 1988, design to measure oxygen saturation in the manner of the "2nd Generation probe" is credible, the March 15, 1988, design nevertheless fails as evidence of conception because it employs an optical fiber to deliver light to the tissue site, which was an inoperative technique at that time for the reasons given above in connection with the November 1987 design and the February 1988 test apparatus.

## **7. Diligence**

As Morrison has failed to prove conception prior to Buschmann's March 24, 1988, benefit date, it is not necessary to consider whether Morrison was diligent during the period running from just before that date up to September 19, 1989, the date of his actual reduction to practice. Nevertheless, we have considered this in the interest of completeness.

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<sup>130</sup> Mannheim Exhibit 44.

Diligence can be shown by evidence of activity aimed at reducing the invention to practice, either actually or constructively, and/or by legally adequate excuses for inactivity. Griffith v. Kanamaru, 816 F.2d 624, 626, 2 USPQ2d 1361, 1362 (Fed. Cir. 1987). It is necessary to account for the entire critical period, Griffith, 816 F.2d at 626, 2 USPQ2d at 1362, with evidence that is specific as to facts and dates. Gould v. Schawlow, 363 F.2d 908, 920, 150 USPQ 634, 644 (CCPA 1966). Although the case law on excuses for inactivity in reducing to practice reveals that the reasonable everyday problems and limitations encountered by an inventor must be considered, Griffith, 816 F.2d at 626, 2 USPQ2d at 1362, efforts to achieve an actual reduction to practice of an invention outside the count will excuse inactivity with respect to the invention of the count only if it is necessary to reduce the inventions to practice in that order. Naber v. Cricchi, 567 F.2d 382, 385, 196 USPQ 294, 296-97 (CCPA 1977), cert. denied, 439 U.S. 826, 200 USPQ 64 (1978); Thompson v. Dunn, 166 F.2d 443, 77 USPQ 49 (1948). As an example of when work on another invention constitutes a satisfactory excuse, Griffith and Naber both cite Keizer v. Bradley, 270 F.2d 396,

398-99, 123 USPQ 215, 217 (CCPA 1959), wherein an inventor was excused for delaying building and testing of the invention of the count, an automatic chroma control circuit for a new color television receiver, until completion of the receiver into which it could be incorporated and tested. "Delays in reduction to practice caused by an inventor's efforts to refine an invention to the most marketable and profitable form have not been accepted as sufficient excuses for inactivity." Griffith, 816 F.2d at 627, 2 USPQ2d at 1363. A short period of unexplained inactivity is sufficient to defeat a claim of diligence. Moller v. Harding, 214 USPQ 724, 729 (Bd. Pat. Int. 1982) (unexplained inactivity for one and one-months defeats claim of diligence); Morway v. Bondi, 203 F.2d 742, 749, 97 USPQ 318, 323 (CCPA 1953) (party not diligent where, following June 7 activity, which was just prior to opponent's June 14 entry into the field, party did not perform other acts until August 1); Ireland v. Smith, 97 F.2d 95, 99-100, 37 USPQ 807, 811 (CCPA 1938) (held not diligent for failing to account for period of three and one-half weeks).

In reviewing Morrison's evidence of diligence during the spring of 1988, we have borne in mind that through June of

1988 Dr. Morrison was teaching full time at the Illinois Mathematics and Science Academy.<sup>131</sup>

Morrison testified that from March 1988 to at least the end of 1988, he was concerned with the issue of how to place an optical fiber in a spiral configuration without damaging the optical fiber and also with the related problem of how much light attenuation was caused by this configuration.<sup>132</sup> In support, Morrison cites copies of numerous orders, invoices, and packing lists for test equipment and supplies he ordered

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<sup>131</sup> J. Morrison, MR 89:7-11.

<sup>132</sup> J. Morrison, MR 91, ¶ 40.

and received during the spring and summer of 1988<sup>133</sup> and on

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<sup>133</sup> Specifically, Dr. Morrison testified (MR 91-98, ¶¶ 42-67) that he ordered or received the following items on or about the following dates:

(a) February 22 - Received from Nippon Electric Glass Company a sample of an optical fiber splicing connector. A copy of the envelope is in evidence as NX 103. Also received from Bentley Computer Products a Bentley Turbo-10 640K computer, for which the packing slip is MX 104.

(b) March 3 - Ordered from Ealing Electro-Optics (Ealing) instrumentation including a photomultiplier for testing optical fibers, specifically for measuring the quantity of light from a source.

(c) March 17 - Received from Action Research Instrument and Equipment Services Inc. (ARIES) a letter (MX 108) regarding payment for an order.

(d) March 28 - Received the following equipment from ARIES: a 1/4 meter Czerny-Turner monochromator (spectrometer); gratings; a control unit; slits; and a fiber optic attachment to be used to test the wavelengths and bandwidths of LEDs. The invoice, which is dated March 23, 1988, is MX 109.

(e) March 29 - Received from Ealing the items ordered on March 3, i.e., instrumentation including a photomultiplier. Receipt is MX 107. (e) April 14 - received fiber optic cable from ARIES. Packing list is MX 122.

(f) May 18 - Received another photomultiplier from Ealing. Packing slip is MX 110.

(g) May 20 - Received the following items from Baxter Healthcare Corporation (Baxter): (1) surgical blades for cutting optical fibers; (2) several power suppliers and miniature lamps to act as light sources; (3) bottles of acetone; (4) a pH concentration/MV/temperature meter; (5) electrodes for detecting/measuring potassium and sodium, of which the latter two items were for development of the second generation probe. Packing list is MX 111.

(h) May 26 - Received a grating from ARIES for use in testing optical fibers. Invoice is MX 112.

(i) June 3 - Received from Baxter a package of surgical blades for cutting optical fibers. Packing list is MX 113.

(continued...)

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<sup>133</sup>(...continued)

(j) June 20 - Sent a package to Jim Babb of Ealing Electrooptics and Irene Galiher of ARIES relating to equipment for the fetal probe project. Shipping order is MX 114.

(k) June 23 - Received a package of bottles from Baxter relating to the fetal probe project. Packing list is MX 115.

(l) July 14 - Received the following supplies from Baxter: (1) a microscope for use in cutting and splicing optical fibers, (2) an auxiliary microscope lens, and (3) a halogen illuminator. Packing list is MX 116.

(m) July 27 - Sent purchase order to Tektronix, Inc. and Newport Corporation for an optimate SFR amp, a 835 optical power meter, and a fiber adapter. Confirmation letter from Tektronix is MX 117.

(n) August 1 Ordered the following from General Fiber Optics, Inc.: (1) optical fibers in sizes 125 and 250 micron, (2) a polishing kit, (3) a one micron fiber, (4) a 500 micron optical fiber, (5) diodes, (6) LEDs, and (7) a laser position adapter. Packing list MX 118. Also sent a confirming purchase order to Newport regarding the on power meter with IEEE interface, one fiber-optic adapter, and one fiber connector. Purchase order is MX 119. Also ordered an oscilloscope and a scope cart from Tektronix for observing waveforms of optical signals and other measurements regarding the fetal probe. Purchase order is MX 120.

(o) August 9 - Received 50-111 fiber optic light guide from ARIES. Invoice is MX 121.

(p) August 23 - Received an oscilloscope and two probes from Tektronix. Packing list is MX 123.

(q) August 24 - Received from Newport the optimate SFR amp, the 835 optical power meter, and the fiber adapter. See page 3 of MX 117.

(r) August 25 - Ordered MetraByte Corporation equipment including a 37 conductor with 18" cable, a D-16 with SPGA gains of 1, 10, 100, and 500, and a screw board terminal. Invoice is MX 124.

(s) August 26 - Purchased wire, 2D subminiature connectors, three LEDs and an F-O set from Radio Shack. Receipt is MX 125.

(continued...)

testimony by him and others about his activities during this time period.

Dr. Morrison explains his activities during the spring months as follows:<sup>134</sup>

44. Over the course of several months, beginning in March of 1988, I was waiting for the new equipment and supplies to arrive at my home so that I could begin some serious testing of optical fibers for the invasive fetal probe. While I was waiting at this time, I began adapting some of the equipment I had already obtained so that I would not have to wait any longer for certain necessary parts. For example, I had already obtained a spectrometer from ARIES (Exhibit 109) [on March 28, 1988] and had obtained a photomultiplier from Ealing Electro-Optics (Exhibit 107) [on March 3, 1988]. In order to effectively test the optical fibers for use in the fetal probe, these two pieces of equipment would have to work cooperatively with one another. However, upon obtaining the spectrometer and photomultiplier, I found that the spectrometer could not communicate with the photomultiplier without a special adapter for connecting the two pieces of equipment. I learned that it would take too long to order the special adapter from a company, so I set about constructing my own adapter to allow the spectrometer to communicate with the photomultiplier.

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<sup>133</sup>(...continued)

(t) August 30 - Received optical fiber ordered from General Fiber Optics, Inc. Packing list is MX 126.

(u) September 3 - Received pin diode and two LEDs from General Fiber Optics, Inc. Packing list is MX 127.

<sup>134</sup> J. Morrison, MR 92-93.



46. During the months of March, April and May 1988, I would periodically show Joe Meyer, Professor at Illinois Mathematics and Science Academy, at my home the rough fetal probe mock-up design I tested in February 1988. I remember that Joe Meyer and his wife would periodically visit my home in the evening for dinner together and that when he visited, I would show Joe Meyer the laboratory I was building in my basement for building and testing the invasive fetal pulse oximetry probe. We typically would look over all of the new equipment that I was acquiring and using to work on the fetal probe project.

Dr. Morrison's testimony that he was building and testing probes during that time period lacks adequate corroboration.<sup>135</sup>

Helen Morrison's testimony that she "was constantly aware of the development activities regarding the fetal oximetry probe from its conception to the present"<sup>136</sup> and that between August 1987 and the filing date of the application in May 1990, her husband never let more than one day pass without working on the fetal probe project, unless she was sick,<sup>137</sup> lacks sufficient specificity as to facts and dates to serve as

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<sup>135</sup> Buschmann does not contend that the documentary evidence are insufficient to prove the orders and receipts of equipment and supplies.

<sup>136</sup> H. Morrison, MR 150, ¶ 16.

<sup>137</sup> H. Morrison, MR 972:19 to 973:8.

adequate corroboration. See Kendall, 173 F.2d at 993, 81 USPQ at 369 (testimony by inventor's wife and son that the inventor from the time of conception worked continuously on development of invention "was not specific as to dates and facts" and therefore "does not constitute the kind of corroboratory evidence required to establish appellant's diligence during the critical period"). See also Gould v. Schawlow, 363 F.2d 908, 920, 150 USPQ 634, 644 (CCPA 1966) (holding insufficient testimony by inventor's wife that her husband continuously worked on the invention at home from the time he said he conceived the idea, citing Kendall, 173 F.2d at 993, 81 USPQ at 369).

While Meyer confirms that during visits to the Morrison home during the spring of 1988 he saw new test equipment and supplies that Dr. Morrison was acquiring to test the invasive fetal probe,<sup>138</sup> he does not confirm that any probes were being built and tested at that time.

Thus, the evidence fails to show that Dr. Morrison or Dr. Yue had made a decision prior to Buschmann's March 24, 1988, benefit date to begin a reduction to practice of one of the

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<sup>138</sup> Meyer, MR 39-40, ¶ 12; MR 162, ¶ 22.

November 1987 and March 15, 1988, probe designs. The fact that prior to that date Dr. Morrison had ordered and received some equipment and supplies does not imply the existence of an intent at that time to reduce to practice of one of the earlier designs, let alone to begin such an effort as soon as the proper equipment could be obtained.

Furthermore, the evidence fails to establish that the equipment and supplies were ordered and used in an expeditious manner.

Also, Dr. Morrison's testimony about making an adapter in order to correct a communication problem between the spectrometer and the photomultiplier is also unconvincing for several reasons. First, it lacks sufficient specificity regarding how these instruments were to be used together in a test, why they failed to communicate, and when the work on the adapter began and was completed. Second, the testimony lacks sufficient corroboration.

Helen Morrison's testimony that Dr. Morrison was always working on the probe. Nor does Meyer confirm that Dr. Morrison was experiencing a communication problem between the

spectrometer and the photomultiplier and a working on an adapter to solve it.

Ted Johnson's testimony that "after March 1988" he periodically worked on the problem of inserting an optical fiber through a hollow spiral needle without collapsing the walls of the fiber<sup>139</sup> does not imply work began during the spring of 1988.

For the foregoing reasons, Morrison has failed to prove diligent activity or an acceptable excuse for inactivity during the spring of 1988, which is sufficient reason in and of itself to defeat his claim of diligence.

Morrison has also failed to prove diligent activity or an excuse for inactivity during the summer of 1988. Dr. Morrison described the activity during this period as follows:<sup>140</sup>

53. Over the course of the summer, I was regularly testing optical fibers. These tests were primarily qualitative since we had not yet obtained some of the better instrumentation we later received in October 1988. The tests centered around comparing oxygen saturation readings for optical fibers placed below the surface of the skin before and after the optical fiber was wound

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<sup>139</sup> T. Johnson, MR 31-32, ¶ 24.

<sup>140</sup> J. Morrison, MR 94.

into a spiral configuration. In these tests, I first obtained an oxygen saturation reading with an optical fiber before inserting the optical fiber into a metal tube. Then I would bend the fiber by passing the optical fiber into and through a metal tube and then wind the metal tube, with the optical fiber extending therethrough, into a corkscrew configuration. Once the metal tube was in this corkscrew configuration, I would test the probe again to see if an oxygen saturation reading could be obtained. I performed this type of test to evaluate: (1) the technique of winding needles around mandrels; (2) different needles of different manufacturers; (3) different wall thicknesses of needles and different gauges; (4) and how each of these different parameters affected the optical fibers. In order to make these tests, we bought thousands of hollow needles, most of them from Baxter Healthcare Corporation.

This testimony lacks clear corroboration. The problem with Helen Morrison's testimony has already been mentioned. Ted Johnson's testimony that sometime during the fall of 1988, he sent Dr. Morrison a sample of an optical fiber wound in a hollow spiral needle establishes only that this act occurred by the end of the fall of 1988. See Haultain v. DeWindt, 254 F.2d 141, 142, 117 USPQ 278, 279 (CCPA 1958) ("where testimony merely places the acts within a stated time period, the inventor has not established a date for his activities earlier than the last day of the period").

In view of Morrison's failure to show diligent activity or an acceptable excuse for inactivity during the

spring and

summer of 1988, there is no need to address the alleged subsequent activities.

**8. Abandonment, suppression, or concealment**

Assuming for the sake of argument that the February 1988 test apparatus represents an embodiment of the probe as it was intended to be used in practice and that the February 1988 tests therefore constituted an actual reduction to practice, the length of time between the reduction to practice and filing (May 29, 1990) is long enough (two years and three months) to create a rebuttable presumption that the invention was abandoned, suppressed, or concealed. See Schindelar v. Holdeman, 628 F.2d at 1342-43, 207 USPQ at 117 (two-year and five-month delay between reduction to practice and filing of application prima facie unreasonable). As a result, the burden would be on Morrison to prove the existence of activities during the delay period which are sufficient to excuse the delay (e.g., efforts to improve or perfect the invention disclosed in the involved patent application). Lutzker v. Plet, 843 F.2d 1364, 1367, 6 USPQ2d 1370, 1371

(Fed. Cir. 1988). Morrison fails to meet this burden with respect to at least the spring and summer of 1988 for the same reasons that he failed to show diligence during that period.

**I. Requests for reconsideration**

A request for reconsideration of a decision by a panel of the Board must specify with particularity the points believed to have been misapprehended or overlooked by the panel in rendering its decision. 37 CFR § 1.658(b). Specifically, a party requesting reconsideration must point to something in the decision which demonstrates the panel overlooked or misunderstood a significant point of argument made in the motion, opposition or reply. It is not enough to show that the argument is not specifically mentioned in the decision; in the absence of a clear indication to the contrary, the parties should presume that all arguments were considered.

**J. Judgment**

As neither Morrison nor Mannheimer has proved an actual reduction to practice prior to Buschmann's benefit date or conception prior that date coupled with diligence running from just before that date up to the party's own filing date, judgment on the issue of priority is hereby entered against

Morrison's and Mannheimer's claims that correspond to the count, i.e., Morrison claims 1-5, 8-24, 27, and 28 and Mannheimer claims 1-11, 18-21, 86-104, and 106-108, which means neither Morrison nor Mannheimer are entitled to a patent including their respective claims. Judgment on the issue of unpatentability over Kapany is hereby entered against Buschmann's claims 1-3, 5-7, 12, 14, 19, 29, and 32. Judgment on the issue of priority is therefore awarded in favor of the remaining Buschmann claims that correspond to the count, i.e., claims 8, 9, 13, 18, 30, and 35-37, which means Buschmann is entitled to a patent including those claims.

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	)	
_____ STANLEY M. URYNOWICZ, JR.	)	
Administrative Patent Judge)	)	
	)	
	)	BOARD OF
_____ JOHN C. MARTIN	)	PATENT APPEALS
Administrative Patent Judge)	)	AND
	)	INTERFERENCES
	)	
	)	
_____ JAMESON LEE	)	
Administrative Patent Judge)	)	



Interference No. 103,197

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